

Exhibit A

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

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BRUCE N. SAFFRAN, M.D., PH.D.,	:	
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<i>Plaintiff and</i>	:	
<i>Counterclaim Defendant</i>	:	
	:	Civil Action No. 2:07-CV-451(TJW)
v.	:	
	:	
	:	
JOHNSON & JOHNSON and CORDIS	:	
CORPORATION,	:	
	:	
<i>Defendants and</i>	:	
<i>Counterclaim Plaintiffs</i>	:	
	:	
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**JOHNSON & JOHNSON AND CORDIS CORPORATION'S INVALIDITY
CONTENTIONS**

Pursuant to the Patent Rules ("P.R.") 3-3 and 3-4 of the Rules of Practice for Patent Cases before the Eastern District of Texas, defendants Johnson & Johnson ("J&J") and Cordis Corporation ("Cordis") (collectively, "Defendants"), by its undersigned attorneys, submit the following Invalidity Contentions ("Invalidity Contentions") to plaintiff Bruce N. Saffran, M.D., Ph.D ("Saffran").

In light of the fact that, as of yet, there has neither been an interpretation of the asserted claim elements of U.S. Patent No. 5,653,760 (the "'760 patent") offered by Saffran nor a Markman hearing and ruling to determine the meaning and scope of the asserted claims, Defendants reserve the right to expand, add, change or otherwise alter its Invalidity Contentions consistent with the Federal Rules of Civil Procedure and the Court's rules.

JOHNSON & JOHNSON AND CORDIS CORPORATION'S
INVALIDITY CONTENTIONS

These Invalidity Contentions are made in response to Saffran's Disclosure of Asserted Claims and Preliminary Infringement Contentions dated September 26, 2008 ("Infringement Contentions") pursuant to P.R. 3-1 and its document production pursuant to P.R. 3-2. As indicated in Saffran's Infringement Contentions, the "asserted claims" are claims 1-11, 13, and 15-18 of the '760 patent.

Defendants' Invalidity Contentions are based in part on Saffran's Infringement Contentions. Defendants' Invalidity Contentions should not be taken as evidence of or construed as an admission that the asserted claim terms have any construction alleged, now or hereafter, by Saffran. To the extent, however, that the claim terms of the alleged claims of the '760 patent have a scope and meaning that is suggested by Saffran, the claims are still anticipated or rendered obvious by the prior art included in these Invalidity Contentions. Correspondingly, nothing in this disclosure should be interpreted to mean that Defendants have adopted a construction for any claim language, or that any claim language requires construction.

Defendants reserve the right to amend and supplement these contentions based on expert discovery yet to be completed.

I. INFORMATION REQUIRED BY PATENT LOCAL RULES

A. Anticipation and Obviousness

Pursuant to P.R. 3-3(a), (b) and (c), Defendants contends that the asserted claims are anticipated or rendered obvious by the prior art set forth in Exhibits A-C to these Contentions. Additionally, these contentions incorporate by reference, in their entirety, all references cited in any of the prior art references.

Exhibit A identifies the prior art references.

Exhibit B identifies the prior art that anticipates the asserted claims or a representative combination of prior art references that render the asserted claims obvious, setting forth the motivation and teachings to combine references.

Exhibit C is a chart that identifies where, in each prior art reference, each element of each asserted claim can be found. Where a single prior art reference includes every element of an asserted claim, that claim is anticipated. Where a combination of prior art references includes the elements of an asserted claim, that claim is obvious. If a particular prior art reference is found not to anticipate a particular asserted claim, that reference renders that claim obvious, either alone or in combination with other prior art disclosing the elements allegedly missing from that reference. The inclusion of a prior art reference as part of an obvious combination of prior art references does not preclude application of that prior art reference as a piece of prior art that anticipates.

These charts are provided for illustrative purposes and may not set forth every place in every reference where a claim element is disclosed. Where elements are disclosed at multiple locations within a single item of prior art, Defendants have not necessarily identified every iteration of every disclosure. In the charts, the absence of an identified location in a

reference where a claim or claim element of the '760 patent is found is not deemed an admission by Defendants that the element is missing from the reference.

Whether a particular claim element is disclosed in the prior art may depend upon the construction of claim terms. Accordingly, Defendants reserve the right to specify further bases of invalidity following the Court's construction of the claims, as permitted by P.R. 3-6. Based upon the information available at this time, Defendants contend that the items in Exhibit C are prior art that anticipate the claims or render them obvious under any likely claim construction. To the extent any reference identified in Exhibit C is not prior art to the asserted claims of the '760 patent, that reference is evidence of simultaneous invention by another.

B. Sections 41 and 112; Inequitable Conduct

Pursuant to P.R. 3-3(a) and (d), Defendants identify the following grounds of invalidity of the '760 patent (under 35 U.S.C. §§ 41 and 112), as well as grounds for unenforceability of the '760 patent:

1. Claims 1-11, 13, and 15-18 of the '760 patent are unenforceable. The '760 patent is unenforceable by reason of the failure of the named inventor, Dr. Bruce N. Saffran ("Saffran"), to comply with his duty of candor in dealing with the United States Patent and Trademark Office ("USPTO"). This inequitable conduct includes material misrepresentations to the USPTO and the failure to disclose information material to patentability. During the prosecution of the '760 patent and in the application itself Saffran (a) misrepresented to the USPTO what he actually did and the characteristics of the claimed invention he observed in order to distinguish his patent application over the prior art; (b) misrepresented the teachings of the prior art – specifically, U.S. Patent No. 5,383,928 (the "Scott patent"); and (c) concealed the existence of prior art relating to "material release means" and misrepresented that concealed art in order to deceive the Examiner into issuing his patent. These acts were deliberately committed

with the intent to deceive the USPTO and render the patent unenforceable as a result of inequitable conduct. Defendants reserve the right to supplement after discovery is taken.

At the time of the alleged conception of the invention claimed in the '760 patent, a substantial body of prior art existed in the stent field.

Among the prior art was the Scott patent, which discloses a polymer sheath for a stent for controlled, directional release of a drug into the adjacent tissue.

At the time the application for the '760 patent was filed, Saffran had filed an application that eventually issued as U.S. Patent 5,466,262 (the "'262 patent") entitled "Malleable Fracture Stabilization Device with Micropores for Directed Drug Delivery." The '262 patent is the parent for the '760 patent.

The '262 patent discloses a dual layer device (containing both microporous and minimally-porous polymer layers) in which drugs were diffused from the microporous layer in a unidirectional manner.

The specification of the '760 patent repeatedly refers to "unexpected" and "surprising" results allegedly "found" or "discovered" by Saffran. The specification of the '760 patent was phrased in such a way – including the use of the past tense – as to lead a reasonable Examiner to believe that experiments were actually performed and those results were actually obtained.

Despite telling the Examiner that results were actually obtained, Saffran was describing prophetic examples.

Saffran falsely represented to the USPTO that that he "found" or "discovered" "unexpected" and "surprising" results in order to distinguish the claimed invention from the prior

art, including the '262 patent and the Scott patent, both of which presented substantial obstacles to the issuance of the '760 patent.

For example, Saffran states that "I have found unexpectedly that if small molecules such as water, urea, bicarbonate, and hydrogen ions are permitted to pass through the device, healing occurs much more quickly." Col. 5:19-22 (emphasis added). These statements misled the Examiner into believing that Saffran performed the experiment, that he had actually observed healing, and that such a result was unexpected in light of the prior art. Saffran never observed such healing as a result of his claimed device.

The specification of the '760 patent repeatedly states that while the '262 patent discloses a two-layered device in which the drug is embedded in the microporous layer, Saffran "found unexpectedly that medicine or other treating materials can be attached directly to the flexible, minimally-porous sheet of the ['262 device]." Col. 14:36-39 (emphasis added). "I have found unexpectedly that, if one affixes medicine directly to the minimally-porous layer, one can bypass the need for the [second] microporous layer entirely!" Col. 8:35-37 (emphasis added). "Surprisingly, I have been able to eliminate the need for the Microporous layer . . . without sacrificing the utility and capability of the parent device." Col. 13:63-66 (emphasis added). Saffran never observed such results with his claimed device.

The specification further states that "[t]he ability of medications to stick to the single sheet of minimally-porous material was surprising, and has provided an exciting series of improvements in both medicine release and in the ease of deployment." Col. 14:39-42 (emphasis added). For example, "I have found that a cardinal feature of the ['262 device] is its ability to restrain macromolecules produced by the fracture within the interfragmentary space. . . . [T]he present invention is remarkable in that it accomplishes this task using a single sheet, rather than a

two layered sheet." Col. 7:38-46 (emphasis added). "Remarkably, the minimally-porous nature of this device serves the same function of kidney dialysis, except in the local fracture environment. . . . Although this dialysis function occurs with the ['262 device], I have found surprisingly that this process occurs more rapidly and more efficiently without the microporous layer in the way." Col. 14:18-28 (emphasis added). In addition, "I have found unexpectedly that if the device is made of a non-resorbable material such as silicone rubber or ethylene vinyl acetate, one can repeatedly pass a needle through the device and inject more medicine into the space between the device and the bone." Col. 17:34-39 (emphasis added). Saffran never observed such results with his claimed device.

Moreover, the specification states that "a surprising and particularly useful sequela of eliminating the microporous layer of the ['262 device] is the ability to make the device considerably thinner . . . [which] provides several new and unexpected applications." Col. 16:66-17:3 (emphasis added). For example, "I have discovered that, if one manufactures the invention as a very thin sheet, one can roll it up and put it into a catheter or introducer needle such that it can be deployed percutaneously." Col. 9:15-18 (emphasis added). "I have found unexpectedly that treating materials can be delivered to a fracture 'inside out' if one places this invention" within the medullary cavity. Col. 17:5-9 (emphasis added). Specifically, "I have found unexpectedly that if I manufacture this invention as a sheet on the order of 200 microns thick, it can be rolled up and placed into a large-bore biopsy needle and advanced into the medullary cavity of a bone." Col. 19:6-9 (emphasis added). Saffran never observed such results with his claimed device.

In addition to touting the advantages of a single-layer design, the '760 patent touts a "medicine release means" for drug delivery whereby a drug attached to a layer "by means of a

chemical bond" is released through hydrolysis of the chemical bond by water or enzymes. Col. 14:44-45, 14:53-15:2, 22:6-17.

The '760 specification specifically distinguishes the claimed invention over the prior art by describing Saffran's "medicine release means" for drug delivery and the "surprising specificity of medicine release provided by the chemical bond [that] is entirely new and unexpected" allegedly discovered during the development of the '760 device. Col. 15:13-18. "A surprising new feature of this device is the improvement in the medicine release kinetics compared to the prior art. . . . I have found that I can achieve a prolonged duration and much more stable rate of efflux from the device when medicine is attached using a hydrolyzable bond." Col. 14:53-61 (emphasis added). "Surprisingly, by using bonds that require an enzyme provided only by osteoblasts, one can delay the release of the medicine from the device until the osteoblasts arrive." Col. 15:2-5 (emphasis added). "Remarkably, one can implant the device of this invention such that one medicine is released by enzymes from Neutrophils . . . a second medicine released by enzymes from fibroblasts . . . and a third medicine which can be released only by osteoblasts." Col. 15:8-13 (emphasis added). Saffran never observed such results with his claimed device.

In total, the specification contains 10 instances in which Saffran states that "I have found" or "I have discovered" a particular use or characteristic of the claimed invention which, he neither found nor discovered. In fact, the descriptors "surprising" or "unexpected" are utilized two dozen times to describe the claimed invention despite, the absence of any surprising or unexpected results. Saffran never observed such results with his claimed device.

During the prosecution of the '760 patent, Saffran relied on the advantages of the single-layer design as the critical distinction between the claimed invention and the '262 device.

In a submission to the USPTO dated February 17, 1996, Saffran cites this feature to overcome a rejection for double patenting in light of the '262 patent, stating, "[t]he device is now a single layer as opposed to a two layered structure. As is mentioned to [sic] in the specification, my ability to combine the features of both layers into a single layer is new." Similarly, in an amendment dated September 4, 1996, Saffran lists the fact that "[t]he device is a single layer rather than two layers (Saffran)" as a point of novelty over the '262 patent.

In contrast to the numerous recitations of "surprising" and "unexpected" features allegedly "found" or "discovered" by Saffran during the development of the claimed invention, the specification fails to disclose any experimental results supporting those claims.

Saffran never conducted any experiments demonstrating that if small molecules such as water, urea, bicarbonate, and hydrogen atoms were allowed to pass through this device, healing would occur much more quickly; that the device could be deployed percutaneously through a needle to introduce drugs into a cavity or the interior of a fracture; that one could affix medicine directly to the minimally porous layer of the '262 device to create a single layer device with the same utility as the parent device and that would permit a more stable rate of medicine release; that the claimed invention could be used to restrain macromolecules within an interfragmentary space or be used as an improved dialysis-like device; or that medicine could be injected into the space between the claimed invention and the treated bone.

Saffran similarly never conducted any experiments in which drugs attached to a device by chemical bonds were released by hydrolysis using water or enzymes. Nor did he conduct any experiments to show that the hydrolysis of chemical bonds by water or enzymes resulted in specificity of drug release or improved drug release kinetics.

In fact, Saffran's own trial testimony in Saffran v. Boston Scientific Corp., 2:05-CV-547-TJW, revealed that that he failed to conduct a single experiment to support the specification's descriptions of work that he claimed to do and results that he claimed to have in the '760 specification:

Q: Okay. Let's talk about how your drug delivery that you do describe and have worked with in pictures in your patent - - now, you've never actually built any device that actually provides directional drug delivery in a live setting, true?

A: Absolutely. I have not done that.

Q: You've never done an experiment in a laboratory where a drug was chemically bonded to a device to show directional delivery in a laboratory through an experiment, have you?

A: You are correct, sir.

(Trial Transcript, Feb. 5, 2008 (AM) 128:13-23).

Saffran represented to the USPTO that he conducted work that he never did and observed results that he never saw with an intent to deceive the patent examiner into issuing his patent over the prior art. A reasonable Examiner would have considered the fact that Saffran never did these experiments and never observed any unexpected or surprising results over the prior art in deciding whether to grant the patent. These repeated false statements were material to the Examiner's determination to grant the patent. The '760 patent is therefore unenforceable due to inequitable conduct.

Saffran also knowingly and intentionally engaged in gross misrepresentations of the teachings of the Scott patent before the USPTO in order to deceive the Examiner into issuing the '760 patent.

The specification of the '760 patent distinguishes the claimed invention from the Scott patent on the basis of the claimed invention's alleged capability for directional drug

delivery. Col. 14:49-52 ("As with the ['262] device (but in distinction to the device of Scott et al. . . .), this device has the capability of directional release."); Col. 20:52-55 ("Furthermore, because [the Scott] sheath does not restrain macromolecules, their sheath cannot have the 'directional drug delivery means' necessary to restrain the medicine that their sheath delivers.").

During the prosecution of the '760 patent, the examiner issued a rejection, finding the claimed invention obvious in light of the Scott patent. (November 17, 1995 Office Action.)

In order to overcome the examiner's rejection, Saffran stated in his February 17, 1996 amendment that while the Scott patent disclosed incorporation of a drug into a stent sheath, it failed to disclose the "directional drug delivery" claimed in the '760 patent which "provides many benefits that are new and unexpected from that of Scott et al." Id. at 9. In fact, "[w]ith the sheath of Scott et al, this [directional drug delivery] would be impossible because their polymer is open to both the bloodstream and the wall of the vessel." Id. (emphasis added). Indeed, Saffran claimed to be "the first to teach of directional drug delivery" using polymers and drugs. Id. at 10.

Saffran continued to make the same false arguments in a submission to the USPTO, dated September 4, 1996, in which he identified the fact that "[t]he device has a directional delivery means rather than multidirectional delivery means (Scott)" as a point of novelty over the Scott patent.

Saffran's representations to the USPTO are gross misrepresentations of Scott and demonstrably false. The Scott patent discloses and claims directional drug delivery. For example, the Scott patent teaches that "one can develop laminate films which deliver [a drug] abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface." 7:56-59. It thus teaches that a particular drug can be released into the arterial wall and away

from the arterial lumen (abluminally) and also that a particular drug can be released into the artery and away from the arterial wall (luminally). Claim 1 discloses a sheath capable of delivering a drug to an "area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted." Scott patent, Col. 10:24-28. The drug is therefore delivered directionally into one area but not the other.

Saffran knew that the Scott patent taught directional drug delivery, knew that this disclosure was material, and intentionally misled the Examiner into believing that Saffran was the first to disclose directional drug delivery. Saffran deliberately and intentionally misrepresented the teachings of the Scott patent in order to deceive the Examiner into issuing the Saffran patent over invalidating prior art. The '760 patent is therefore unenforceable due to inequitable conduct.

To distinguish the claimed invention over prior art, including the '262 and Scott patents, the '760 patent touts a "medicine release means" for drug delivery whereby a drug attached to a layer "by means of a chemical bond" is released through hydrolysis of the chemical bond by water or enzymes. Col. 14:44-45, 14:53-15:2, 22:6-17.

The '760 specification states that "[w]hereas both the stent sheath of Scott et al. . . . and the microporous layer of the ['262 device] rely on the random diffusion of medicine from micropores, I have found that I can achieve a prolonged duration and much more stable rate of efflux from the device when medicine is attached using a hydrolyzable bond." Col. 14:55-61. The specification further asserts that "[t]he method of medicine release by chemical bond is also a highly significant improvement over the prior art. Prior art references all rely on the efflux of treating materials from micropores to deliver medicine." Col. 22:6-10 (emphasis added). Indeed, the specification goes so far as to assert that controlled drug release "is impossible using

the prior art, and it represents a major advance in fracture treatment." Col. 15:18-20 (emphasis added).

Saffran relies on this "surprising specificity of medicine release provided by the chemical bond [that] is entirely new and unexpected" allegedly discovered during the development of the '760 device to distinguish the claimed invention from all prior art devices. Col. 15:13-18 (emphasis added).

In fact, drug release by hydrolysis of chemical bonds was well known in the prior art at the time the patent was filed. At the time he filed the '760 patent, Saffran knew that drug release by hydrolysis of chemical bonds was well known.

For example, United States Patent 4,356,166 (the "Peterson patent"), filed in 1978, discloses a "time-release chemical delivery system in which a bioactive compound is attached to a polymeric biodegradable carrier by a hydrolyzable bond." Abstract, Peterson patent.

Similarly, publications from the early 1980s and 90s describe the hydrolysis of chemical bonds to achieve controlled drug release. See, e.g., Robert Langer, *Controlled Release: A New Approach to Drug Delivery*, Technology Review, 26-34 (April 1981) ("Langer I"); Robert S. Langer, Polymers and Drug Delivery Systems in Long-Acting Contraceptive Delivery Systems 22 (Gerald I. Zatuchni, et al., eds. 1984) ("Langer III"); Robert Langer & Nikolas Peppas, *Chemical and Physical Structure of Polymers as Carriers for Controlled Release of Bioactive Agents: A Review*, Rev. Macromol. Chem. Phys. C23(1), 61 (1983) ("Langer & Peppas"); Robert S. Langer & Nikolas A. Peppas, *Present and Future Applications of Biomaterials in Controlled Drug Delivery Systems*, Biomaterials, 2:201-14 (Oct. 1981) ("Langer

& Peppas II"); Robert Langer, *New Methods of Drug Delivery*, Science 249:1527-1533 (Sept. 28, 1990) ("Langer VII").

Significantly, details regarding the use of the "medicine release means" described in the prior art are portrayed in the '760 specification as novel advances made by Saffran. For example, the '760 specification states that in contrast to "the random diffusion of medicine from micropores, I have found that I can achieve . . . [a] much more stable rate of efflux from the device when medicine is attached using a hydrolyzable bond." Col. 14:59-61 (emphasis added). The prior art, however, discloses that "[t]o achieve near constant release, the cleavage of the drug from the polymer must be the rate-limiting step." Langer & Peppas at 100 (emphasis added). The '760 specification also states that "[r]elease rates can be adjusted simply by varying the linkage between the medicine and the device." Col.14:64-65 (emphasis added). Meanwhile, the prior art discloses that a "spacer group [linking the drug to the polymer] may be used to affect the rate of release." Langer I at 28 (emphasis added); Langer & Peppas at 100. In addition, the '760 specification states that "[i]n the preferred embodiment, these linkages are hydrolyzable by the water within the interfragmentary space; however the linkages can be made of any suitable bond, e.g., a bond that requires a particular enzyme for hydrolysis." Col. 14:65-15:2 (emphasis added). At the same time, the prior art discloses a device where "a drug is chemically bound to a polymer backbone-chain and is released by hydrolytic or enzymatic cleavage." Langer I at 27 (emphasis added); Langer & Peppas at 100 (same); see also Langer II at 30 ("Release occurs when water reacts to break those bonds, thereby freeing the drug...[A]n enzymatic reaction could [also] break the drug-polymer bonds.").

Saffran has both doctorate and medical degrees and his Ph.D. research involved delivery of drugs using polymers. Saffran knew of the prior art and its materiality but

deliberately and intentionally mischaracterized the state of knowledge in the field of controlled drug release and concealed the existence of material prior art disclosing the claimed "material release means" (Col. 22:40) in order to deceive the Examiner into issuing his patent.

A reasonable Examiner would have considered the lack of difference between the prior art and the invention claimed in the '760 patent material. A reasonable Examiner would have considered the undisclosed prior art material.

The examples of misrepresentations made by Saffran during the prosecution of the '760 patent and in the patent itself described herein establish a pattern of misconduct that demonstrates an intent to deceive the USPTO. Furthermore, these misrepresentation were material in light of the invalidating prior art that existed in the field at the time the '760 patent was filed. The '760 patent is therefore unenforceable due to inequitable conduct.

Further, the '760 patent may be unenforceable due to inequitable conduct for intentionally false and misleading statements made to the USPTO in order to revive the patent.

2. Claims 1-11, 13, and 15-18 of the '760 Patent are invalid for indefiniteness for claiming "material release means." The term "material release means" is a means plus function term, which must be construed according to 35 U.S.C. §112 para. 6. In a prior claim construction, Judge Ward identified the structure of "material release means" as "chemical bonds and linkages." This structure does not meet the minimal disclosure necessary to make the claims definite. Simply reciting "chemical bonds" without providing some detail about the means to accomplish the function of release is not enough. Because general chemical bonds can be created and released in very different ways and in an almost infinite number of combinations, simply disclosing "chemical bonds" as the structure designated to perform a particular function does not limit the scope of the claim to the "corresponding structure, material, or acts" that

perform the function, as required by §112 para. 6.

3. Claims 1-11, 13, and 15-18 of the '760 Patent are invalid for lack of written description because one of ordinary skill in the art reading the specification of the '760 Patent could not reasonably conclude that the inventor was in possession of: 1) porous stents with uncovered mesh holes, 2) treating material/drug located anywhere other than the surface of the device, 3) two layer devices, or 4) lack of structure for "material release means."

1. Disclaimer of Porous Stents With Uncovered Mesh Holes.

The specification of the '760 Patent criticizes and disclaims porous stents with uncovered mesh holes, such as the accused Cypher stent. The specification summarizes what Saffran viewed as lacking in the art: "Clearly, what is needed is a device that can restrain macromolecules but allow free passage of small molecules." '760 Patent, col.5:31-33. Saffran stated his belief that macromolecules aid in healing and high concentrations are necessary for proper healing. *Id.* at col.2:12-23. The invention of the '760 Patent allegedly solves the problem of "insufficient growth-promoting macromolecules" by restraining the movement of macromolecules. *Id.* at col.2:18-20, 40-44, 59-60. The "means for minimal porosity and macromolecular containment" is "a critical aspect of the present invention," '760 Patent, col.14:8-10, and an "exceedingly important feature." *Id.* at col.20:49-52; see also id. at col.5:7-8 (discussing the "critical aspect of minimal porosity"). In the '760 Patent specification, Saffran criticizes and distinguishes medical devices that are porous, such as porous stents with uncovered mesh holes, because those devices are unable to restrain macromolecules.

The '760 Patent specification criticizes prior art medical devices that are porous because macromolecules, which are "orders of magnitude smaller than cells," are "not restrained within the interfragmentary space" and instead are "free to exit the interfragmentary space and pass

unhindered into the surrounding tissue." '760 Patent, col.3:50-67. The specification specifically criticizes uncovered stents as "porous" to macromolecules and as creating problems that the invention is designed to overcome. '760 Patent, col.20:10-58.

Saffran's specification is critical of stents with uncovered holes between their struts. It denigrates such stents as "porous meshes" that do not provide the benefits of the invention because of their uncovered openings or "mesh holes." '760 Patent, col.20:22-38. The specification states that "[c]urrent vascular stents are porous meshes made of either metal, e.g., Gianturco-Rosch COOK-ZTM stent (FIGS 8a and 8b) and the WallstentTM, or ... plastic." Id. at col.20:22-24; see also id. at col.9:26-27 (describing "current state-of-the-art stents" as "porous meshes").

The specification uses reference numeral 27 to designate the "mesh holes," *i.e.*, the "[s]pace or hole between the mesh" created by the struts 29 of these prior art stents ('760 Patent, col.12:58-59). As shown in Fig. 8c and as described in the specification, the mesh holes 27 of prior art stents are so large that macromolecules 8 can easily move through them into the lumen (or opening) of a blood vessel 38. Id. at col.20:22-33.

Saffran criticized the structure of stents as undesirable. Saffran's specification criticizes porous prior art stents as creating problems that his invention is meant to solve: "Because the smallest holes [between the bars of a mesh stent] are tens of microns in diameter, ... large macromolecules are free to move through them," '760 Patent, col.20:34-38, into the artery, where the helpful macromolecules will be "swept away by moving blood." Id. at col.20:10-19. As a result, porous stents lack an "exceedingly important" feature of the invention, id. at col.20:49-51, the "means to restrain the macro-molecules elaborated by the healing tissue ... in the space adjacent to the injured blood vessel wall." Id. at col.20:59-62.

The specification's discussion of prior art U.S. Patent No. 5,383,928 to Scott is further evidence of the disclaimer. Scott sought to improve upon stents that have a drug/polymer coating on their metal struts. Instead of coating a stent's struts with a drug/polymer combination, Scott proposed an alternative – using a "sheath" with a drug/polymer combination, for "encompassing" all or part of the stent. Scott '928 Patent, col.4:58-63, col.5:29-30. Saffran stated in the '760 specification that Scott's "stent sheath" "can cover the metallic mesh of a porous stent," '760 Patent, col.20:38-42, as illustrated in Fig. 8d of Saffran's '760 patent, id. at col.11:26-27.

Although the specification describes Scott's "stent sheath" as a "significant advance," '760 Patent, col.20:38-48, it criticizes Scott because the sheath only "somewhat limit[s] [the] porosity" of prior art stents, id. at col.20:40-42, and thus "does not have means to restrain macromolecules between [the] sheath and the vessel wall." Id. at col.20:46-55 (emphasis added). Saffran viewed this drawback as significant because "the ability to restrain the macromolecules elaborated by the healing tissue is a[n] exceedingly important feature." Id. at col.20:49-51. Fig. 8e illustrates this "exceedingly important" feature of the invention. Id. at col.20:49-51. This figure depicts the same prior art stent shown in Fig. 8c, but with "the present invention wrapped around" the stent, completely covering its mesh holes 27. Id. at col.11:28-30. Reference numeral 1 indicates Saffran's "[s]ingle-layered, flexible, minimally-porous sheet having macromolecular restraintment means," id. at col.12:21-22. Fig. 8f is a "cross-section view" of the same embodiment, id. at col.11:34-35 and shows that the device 1 restrains the macromolecules 8 from moving through the spaces between the bars 29 of a prior art stent.

Fig. 9b illustrates a stent "wrapped by the invention." '760 Patent, col.11:62-64. "[T]he invention [1]" is "being used to coat a stent in the common bile duct 45," id. at col.21:5-10, with

"the device of the present invention ... wrapped around a stent in much the same way as is shown in Fig. 8d [which depicts Scott's prior art 'stent sheath']," id. at col.11:54-57; see also id. at col.11:62-64. As depicted in Fig. 9b, any mesh holes in the "invention-coated" stent are completely and continuously covered by the device of Saffran's invention, "substantially restricting the flow of macromolecules" into the body passageway. Id. at col.21:5-28.

The specification does not depict or suggest any embodiment in which the mesh holes of a porous stent remain uncovered and permit macromolecules to pass without restriction through the holes between the stent's bars and into the bloodstream. Throughout the specification, Saffran characterizes his invention according to its ability to restrain macromolecules. Saffran criticizes prior art porous stents with uncovered mesh holes due to the lack of restraint of macromolecules through the struts of the stent. Due to this disclaimer and criticism of porous stents with uncovered mesh holes, no person of ordinary skill would conclude that Dr. Saffran was in possession of a porous stent with uncovered mesh holes.

2. Treating Material/Drug Must be Located at the Surface of the Invention.

The '760 Patent only discloses treating materials attached at the surface of the layer and disclaims and criticizes other devices where drug is not attached at the surface. Saffran describes the discovery of attaching drug to the surface as a major part of his invention. The specification of the '760 Patent is limited to devices with treating material attached at the surface.

The specification of the '760 Patent criticizes prior art devices for containing medicine within material instead of affixing the medicine to the surface. Saffran's earlier patent, U.S. application Ser. No. 08/114,745 which issued as U.S. Patent No. 5,466,262 ("the '262 Patent"), disclosed a two layered device that contained "a first layer of minimally porous material affixed to a second layer of medication-containing material." '760 Patent, col.5:36-43. Saffran criticized

the method for release of medicine from within the second layer material, stating in the specification that it would be "desirable to have the treating material released in a more controlled manner than mechanical efflux from pores." Id. at col.6:18-20.

Scott's '928 Patent was also criticized for its method of drug release by diffusion of the drug from within material. "Whereas both the stent sheath of Scott et al. (FIG. 8d) and the microporous layer of the Malleable Fracture Stabilization Device with Micropores, 2, rely on the random diffusion of medicine from micropores, I have found that I can achieve a prolonged duration and much more stable rate of efflux from the device when medicine is attached using a hydrolyzable bond." '760 Patent, col.14:55-61.

Saffran claimed that affixing the treating material to the surface of the layer was seen as an improvement by Saffran. Indeed, the invention of the '760 Patent could not be a single microporous layer without affixing the treating material to the surface. The '262 Patent's "Malleable Fracture Stabilization Device requires that a second microporous layer containing a treating material be affixed to the minimally-porous layer." '760 Patent, col.8:30-40. Saffran disclaimed the use of a treating material within any layer and specifically stated the benefits of attaching the treating material of the surface: "I have found unexpectedly that, if one affixes medicine directly to the minimally-porous layer, one can bypass the need for the microporous layer entirely! For example, if one chemically binds the medicine to the minimally-porous layer using a particular type of chemical bond, the bonds will be hydrolyzed in situ according to a specific rate constant." Id.

Saffran claimed that affixing the treating material to the surface was an unexpected and surprising improvement over the prior art. "Attachment of a treating material to the device of the invention: I have found unexpectedly that medicine or other treating materials can be attached

directly to the flexible, minimally-porous sheet of the Malleable Fracture Stabilization Device with Micropores. The ability of medications to stick to the single sheet of minimally-porous material was surprising, and has provided an exciting series of improvements in both medicine release and in the ease of deployment." '760 Patent, col.14:34-42.

The specification makes clear that the attachment of treating material to the surface of the invention "is entirely new and unexpected." '760 Patent, col.15:13-20. The prior art's reliance on diffusion of drugs through a material is criticized and described as an inferior method of release. Saffran states that the "above-described feature of specific drug release (by attaching it to the surface) is impossible using the prior art, and it represents a major advance in fracture treatment." Id. In addition to criticizing the prior art method of drug release by diffusion, the specification also characterizes the invention according to the attachment of treating material to the surface of the layer.

Saffran describes the invention of the '760 Patent as an improvement on the '262 Patent. It is an object of the '760 Patent "to provide a unique method and apparatus that can perform the essential healing features of the Malleable Fracture Stabilization Device with Micropores for Directed Drug Delivery using only a single layer of minimally-porous layer to which has been affixed a treating material directly on its surface." '760 Patent, col.7:1-6; see also id. at col.8:25-29, col.1:24-26. Affixing the treating material to the surface was essential for the invention.

The '760 Patent focuses on improved healing, by both restraining macromolecules and "by the attachment of a treating material (12), either mechanically or by chemical bond (24), to one surface of the device." '760 Patent, Abstract. "When a treating material is affixed to the provided device, the device can deliver it directly and specifically to the fracture site. Medicines, when they are diffusable macromolecules, can be held to the single layer using chemical bonds

such that medicines are released according to a rate constant rather than random diffusion through a matrix of pores." Id. at col.6:34-40.

Treating materials must be attached to the surface of the device due to the microporous nature of the layer. Layers that are microporous restrain the movement of macromolecules and treating materials. "When the method of use contains the additional step of affixing a medicine to the flexible macromolecular-containment device prior to implantation, additional healing benefit can be realized because, not only are the macromolecules produced by the fracture contained within the interfragmentary space, but additional medicines beneficial to the healing process can be delivered directly and preferentially into the fracture site." '760 Patent, col.13:25-32. If treating materials were placed within a microporous layer, then the treating materials could never escape the layer to reach the area to be treated. Treating materials, like other macromolecules, are restrained by the layer.

Every single figure that shows a treating material only shows that treating material affixed to the surface of the layer. Reference 12 is defined as: "12) Treating material affixed to single-layered, flexible, minimally-porous sheet." '760 Patent, col.12:40-41. It is important to have the treating material at the surface of the invention because the side with the affixed treating material is placed adjacent to the injury site so the drug can treat the affected area. See id. at col.10:10-22; col.10:40-46; col.11:28-33; col.11:47-52; .

For example, Figure 3b shows the "medication containing side is adjacent to the injury site. Because the device is impermeable to both the treating material and the macromolecules produced by the fracture, the concentration of both types of macromolecules is substantially higher in the interfragmentary space compared to that within the surrounding soft tissues." Id. at col.10:10-22. Similarly, FIG. 5b shows the invention is placed so that "the medicine is

intimately associated with the abnormal tissue. The macromolecular containment means serves to keep the medicine where it is most needed." '760 Patent, col.10:40-46. Fig. 8E is a side view of the invention wrapped around a stent and shows "unidirectional delivery of medicine from the outer surface taking advantage of the macromolecular containment means of the minimally-porous sheet." Id. at col.11:28-33; see also id. at col.11:47-52.

In addition to the evidence from the specification and the figures, the Examiner also understood the scope of the '760 Patent to be limited to treating materials attached to the surface of the layer. In the Notice of Allowance, the Examiner stated the reasons for allowance: "The claimed invention embodies a unique method of fracture stabilization and restraint of interfragmentary molecules using a single flexible minimally porous sheet layer, the surface of which has a treating material applied directly thereto." '760 Patent, Paper 17, Notice of Allowability, pg. 7.

There is no written description of a treating material attached to anything other than the surface of the layer. There is also no written description of a treating material within a layer, in fact it is disclaimed. Dr. Saffran did not have possession of anything broader than the attachment of treating materials at the surface. Based on statements in the specification and the Examiner's statement of reasons for allowance, a person of ordinary skill in the art would have understood that the scope of the '760 Patent is limited to treating materials placed at the surface of the layer and nowhere else.

3. Disclaimer of Two Layer Devices.

The specification of the '760 Patent characterizes the invention as a single layer and disclaims and criticizes two layer devices. One skilled in the art would recognize the disclosure was limited to a single layer and two layer devices were disclaimed.

In the patent and prosecution history, Saffran disclaims dual-layer devices in order to distinguish his earlier patent, directed to dual-layer devices. Saffran emphasizes that his present invention is only a single layer and that a single-layer device is a significant, surprising and unexpected improvement over his earlier invention. During prosecution, Saffran repeatedly relied on "a single layer" as a point of novelty over his prior patent. The Examiner relied on and emphasized this element in the reasons for allowance. For all these reasons, "a layer" should be construed as "a single layer."

Saffran criticized his previous invention because it used two layers. The following passages further illustrate his disclaimer:

The applicant of the present invention, in U.S. patent application Ser. No. 08/114,745, filed Aug. 30, 1993 and entitled "Malleable Fracture Stabilization Device with Micropores for Directed Drug Delivery" has disclosed a two layered device that contains a first layer of minimally porous material affixed to a second layer of medication-containing material. col.5:36-42.

Although the "Malleable Fracture Stabilization Device with Micropores for Directed Drug Delivery", solves many problems not addressed by the prior art, several improvements in design can be made to make it even more desirable as a healing agent. Specifically, it would be desirable to make the device ***a single layer*** so that less foreign material be implanted into the patient. . . . 6:13-23 (emphasis added).

My Malleable Fracture Stabilization Device requires that a second microporous layer containing a treating material be affixed to the minimally-porous layer. ***I have found unexpectedly that***, if one affixes medicine directly to the minimally-porous layer, ***one can bypass the need for the microporous layer entirely!*** 8:30-37 (emphasis added).

This single layered design has, by itself, several advantages over the two layered Malleable Fracture Stabilization Device with Micropores. First, because the need for a separate microporous layer has been eliminated, the patient has less foreign material implanted in his/her body. Second, the material delivery rate is much more uniform when a chemical reaction determines the release rate rather than passage through a mechanical pore. Third, because the need for an entire layer has been eliminated, the device can be manufactured much thinner than the two-layered Malleable Fracture Stabilization Device with Micropores. 8:49-59 (emphasis added).

FIG. 1b This is a side view of the two-layered Malleable Fracture Stabilization Device with Micropores for Directed Drug Delivery (prior art, U.S. application Ser. No. 08/114,745, Filing date Aug. 30, 1993). Note that it is thicker and contains more structural materials than the present invention. 9:56-61.

FIG. 1a shows the device, 1, in profile prior to implantation into a patient. *Note that it is a single, thin layer of material as opposed to the structure of the Malleable Fracture Stabilization Device with Micropores for Directed Drug Delivery* (U.S. patent application Ser. No. 08/114745, filed Aug. 30, 1993) shown in FIG. 1b. *Surprisingly, I have been able to eliminate the need for the Microporous layer, 2, without sacrificing the utility and capability of the parent device.* The principal embodiment of the present invention is a sheet with the same characteristics as the malleable, minimally-porous anchoring component, 3, of the Malleable Fracture Stabilization Device with Micropores. As the reader will appreciate, *the device of the present invention is much thinner than the Malleable Fracture Stabilization Device with Micropores, a fact that will yield surprising advantages when it comes time to deploy it in a patient.* 13:58-14:6 (emphasis added).

A surprising and particularly useful sequela of eliminating the microporous layer of the Malleable Fracture Stabilization Device with Micropores, is the ability to make the device considerably thinner. This ability provides several new and unexpected applications which I will discuss below. 16:66-17:3 (emphasis added).

The ability to attain the healing power of the Malleable Fracture Stabilization Device with Micropores using a single sheet is a significant improvement in design because the device can now be made much thinner. The thinness of the device provides the unexpected ability to much more easily apply the healing benefits of the Malleable Fracture Stabilization Device with Micropores to the medullary canal, hollow organs, and blood vessels. 21:60-67 (emphasis added).

The following passages from the specification demonstrate that Dr. Saffran's disclosure is limited to a single layer device:

The device is composed of *a single sheet* of material (1) that in its principal embodiment is supplied as a thin, pliable, fabric that is flexible in three dimensions and is minimally porous to macromolecules. Abstract (emphasis added).

The present invention is provided as *a single-layered*, malleable fixation *device*... 6:26-31 (emphasis added).

Medicines, when they are diffusable macromolecules, can be held to the *single layer* using chemical bonds such that medicines are released according to a rate

constant rather than random diffusion through a matrix of pores. 6:36-40 (emphasis added).

It is a principal object of the present invention to provide a unique method of tissue stabilization and containment of interfragmentary macromolecules using a single, flexible minimally porous sheet. 6:64-67 (emphasis added).

It is a further object of the present invention to provide a unique method and apparatus that can perform the essential healing features of the Malleable Fracture Stabilization Device with Micropores for Directed Drug Delivery ***using only a single layer*** of minimally-porous layer to which has been affixed a treating material directly on its surface. 7:1-6 (emphasis added).

The invention is a unique method of fracture stabilization and way to restrain interfragmentary macromolecules ***using a single, flexible minimally porous sheet.*** 7:34-36 (emphasis added).

Although the macromolecular restraintment means of the Malleable Fracture Stabilization Device with Micropores is a feature of its minimally-porous layer, ***the present invention is remarkable in that it accomplishes this task using a single sheet, rather than a two layered sheet.*** 7:42-46 (emphasis added).

Therefore, ***the elimination of an entire layer while maintaining function is a highly significant improvement in design.*** By eliminating a large percentage of the mass of prosthetic necessary to perform the same function, the device used in the present invention becomes even more hospitable to both the patient and the surgeon. 7:47-56 (emphasis added).

According to one embodiment, ***a single sheet*** that is flexible in three dimensions and minimally porous to macromolecules, is wrapped around or affixed to a fractured tissue. 7:57-60 (emphasis added).

The invention is a unique method and apparatus that can perform the essential healing features of the Malleable Fracture Stabilization Device ***using only a single layer*** of minimally-porous material to which has been affixed a treating material directly on its surface. 8:25-29 (emphasis added).

FIG. 1a ***This is a side view of the device of the present invention provided as a sterile, single-layered, flexible, minimally-porous sheet*** having macromolecular restraintment means. Note that ***it is a single layer of minimally-porous material, rather than a two layered structure.*** 9:51-55 (emphasis added).

FIG. 1c This is a top view of ***the present invention, which is provided as a single-layered, flexible, minimally-porous sheet*** having macromolecular restraintment means. 9:62-64 (emphasis added).

FIG. 4a This is a side view of *the single-layered*, flexible, minimally-porous *sheet* with macromolecular restraint means wrapped partially around a comminuted bone fracture. 10:23-26 (emphasis added).

Single-layered, flexible, minimally-porous *sheet* having macromolecular restraint means [marked as 1 in figures]. 12:21-22 (emphasis added).

Treating material affixed to *single-layered*, flexible, minimally-porous *sheet*. 12:40-41 (emphasis added).

Positively-charged, *single-layered*, flexible, minimally-porous *sheet*. 12:52-53 (emphasis added).

The *device, 1, is composed of a single sheet* of material that in its principal embodiment is supplied as a thin, pliable, fabric that is flexible in three dimensions by human hands. 13:39-41 (emphasis added).

The ability of medications to stick to the *single sheet* of minimally-porous material was surprising, and has provided an exciting series of improvements in both medicine release and in the ease of deployment. 14:39-42 (emphasis added).

He/she then selects *the Single, Flexible, Minimally Porous Sheet of this invention* to which has been affixed a combination of penicillin, bone morphogenetic protein, Fibroblast Growth Factor, and Transforming Growth Factor Beta, to stabilize and prevent resorption of the minor fragments, 5. 16:17-23 (emphasis added).

Accordingly, the reader will see that this device and the method of its use address the principal problem in healing serious bone fractures. . . . *Surprisingly, this can be accomplished using a single layer* of minimally-porous material wrapped around the fracture. 21:49-59 (emphasis added).

Figures 1a, 1c, 2a, 3a-b, 4a-c, 5a-5d, 6a-b, 7b-c, 8e-h, 9a-e; Cf. to 1b (prior art).

It is also clear from the prosecution history that Saffran's claimed invention is limited to a single layer device. Saffran's prior patent describes devices with two layers. To distinguish that patent, Saffran repeatedly stated that his device was novel because it "is a single layer rather than two layers." '760 Patent, Paper 8 at 6; Paper 13 at 9. In response to a double patenting rejection, Saffran stated: "The device is now a single layer as opposed to a two layered structure. As is mentioned in the specification, my ability to combine the features of both layers into a single layer is new." *Id.* at Paper 4 at 7. In the reasons for allowance, the Examiner stated: "The

claimed invention embodies a unique method of fracture stabilization and restraint of interfragmentary molecules using a single flexible minimally porous sheet layer, the surface of which has a treating material applied directly thereto." Id. at Paper 17 at 7 (emphasis in original).

The '760 Patent only discloses a single layer device. Based on Saffran's criticisms of devices with two layers and characterization of the invention according to its single layer, a person of ordinary skill in the art would conclude that Dr. Saffran was not in possession of two layer devices and indeed disclaimed them.

4. Failure of Specification to Disclose Structure of "material release means".

The claims of the '760 Patent include the means plus function term "material release means," which must be construed according to 35 U.S.C. §112 para. 6. Under §112 para. 6, "[a]n element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." In a prior claim construction, Judge Ward identified the structure of "material release means" as "chemical bonds and linkages." This structure does not meet the minimal disclosure required by §112, para. 6. Simply reciting "chemical bonds" without providing some detail about the means to accomplish the function of release is not enough.

4. Claims 1-11, 13, and 15-18 of the '760 Patent are invalid for lack of enablement, because the specification of the '760 Patent is not sufficient to teach one of ordinary skill in the art to make "material release means." There is no teaching of how to make the connections between the drug and the polymer and how to release the treating material after it is

attached. Simply stating "chemical bonds" is not enough. The structure of specific "chemical bonds" must be taught so that one of skill in the art would have understood that disclosure to encompass chemical bonds to perform the release function and been able to implement such bonds, not simply whether one of skill in the art would have been able to create any general chemical bond.

II. DOCUMENT PRODUCTION REQUIRED BY PATENT RULES

Pursuant to P.R. 3-4, Defendants are producing documents to Saffran under separate cover with the following Bates ranges: CSF00000001 to CSF00457380.

Some of the documents being produced are affixed with "Highly Confidential" designations, denoting "outside attorneys eyes only." Until a protective order is entered, the highly confidential nature of this material is protected by Rule 2-2 of the Patent Local Rules of the United States District Court for the Eastern District of Texas.

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Respectfully submitted,

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EXHIBIT A

The listed references anticipate or, in the alternative, render the asserted claims obvious at the time they were made. For the purpose of Defendants' Preliminary Invalidity Contentions pursuant to P.R. 3-3, the items of prior art are set forth below. Further detail for selected representative items of prior art from this list are provided in Exhibits B and C.

1. U.S. Patent No. 5,383,928, issued Jan. 24, 1995 ("Scott '928").
2. U.S. Patent No. 5,282,823, issued Feb. 1, 1994 ("Schwartz '823").
3. U.S. Patent No. 4,356,166, issued Oct. 26, 1982 ("Peterson '166").
4. U.S. Patent No. 5,637,113, issued June 10, 1997 ("Tartaglia '113").
5. U.S. Patent No. 5,545,208, issued August 13, 1996 ("Wolff '208").
6. European Patent Office Publication 0 623 354 B1, published September 11, 1994 ("Berg '354").
7. U.S. Patent No. 5,464,450, issued November 7, 1995 ("Buscemi '450").
8. U.S. Patent No. 6,120,546, issued September 19, 2000 ("Ding '536").
9. U.S. Patent No. 5,591,227 issued January 7, 1997 ("Dinh '227").
10. U.S. Patent No. 5,512,055 issued April 30, 1996 ("Domb '055").
11. U.S. Patent No. 5,019,096 issued May 28, 1991 ("Fox '096").
12. U.S. Patent No. 5,716,981 issued February 10, 1998 ("Hunter '981").
13. U.S. Patent No. 5,616,608 issued April 1, 1997 ("Kinsella '608").
14. U.S. Patent No. 5,152,782 issued October 6, 1992 ("Kowligi '782").
15. U.S. Patent No. 5,562,922 issued October 8, 1996 ("Lambert '922").
16. International Application WO 94/21308 published September 29, 1994 ("Lambert '308").

17. International Application WO 94/21309 published September 29, 1994 ("WO 94/21309").
18. U.S. Patent No. 5,288,711 issued February 22, 1994 ("Mitchell '711").
19. U.S. Patent No. 5,516,781 issued May 14, 1996 ("Morris '781").
20. European Patent Application 0 551 182 A1 published July 14, 1993 ("Morris '182").
21. U.S. Patent No. 5,474,563 issued December 12, 1995 ("Myler '563").
22. U.S. Patent No. 5,102,417 issued April 7, 1992 ("Palmaz '417").
23. U.S. Patent No. 4,389,330 issued June 21, 1983 ("Tice '330").
24. U.S. Patent No. 4,464,317 issued August 7, 1984 ("Thies '317").
25. U.S. Patent No. 4,530,840 issued July 23, 1985 ("Tice '840").
26. U.S. Patent No. 4,542,025 issued September 17, 1985 ("Tice '025").
27. U.S. Patent No. 4,622,244 issued November 11, 1986 ("Lapka '244").
28. U.S. Patent No. 4,675,189 issued June 23, 1987 ("Kent '189").
29. U.S. Patent No. 4,897,268 issued January 30, 1990 ("Tice '268").
30. U.S. Patent No. 5,011,486 issued April 30, 1991 ("Aebischer '486").
31. U.S. Patent No. 4,164,560 issued August 14, 1979 ("Folkman '560").
32. U.S. Patent No. 4,591,496 issued May 27, 1986 ("Cohen '496").
33. U.S. Patent No. 4,713,243 issued December 15, 1987 ("Schiraldi '243").
34. U.S. Patent No. 4,842,868 issued June 27, 1989 ("Helwing '868").
35. U.S. Patent No. 4,877,029 issued October 31, 1989 ("Valentini '029").
36. U.S. Patent No. 4,879,135 issued November 7, 1989 ("Greco '135").
37. U.S. Patent No. 4,931,279 issued June 5, 1990 ("Bawa '279").

38. U.S. Patent No. 5,106,627 issued April 21, 1992 ("Aebischer '627").
39. U.S. Patent No. 5,260,066 issued November 9, 1993 ("Wood '066").
40. U.S. Patent. No. 6,193,746 B1 issued February 27, 2001 ("Strecker '746").
41. U.S. Patent No. 5,900,246 issued May 4, 1999 ("Lambert '246").
42. U.S. Patent No. 5,834,029 issued November 19, 1998 ("Bellamkonda
'029").
43. U.S. Patent No. 5,449,382 issued September 12, 1995 ("Dayton '382").
44. International Application WO 95/03036 published February 2, 1995
("Burt '036").
45. U.S. Patent No. 5,61,586 issued October 28, 1997 ("Goldin '568").
46. U.S. Patent No. 5,356,630 issued October 18, 1994 ("Laurencin '630").
47. U.S. Patent No. 4,941,877 issued July 17, 1990 ("Montano '877").
48. U.S. Patent No. 5,037,656 issued August 6, 1991 ("Pitt '656").
49. U.S. Patent No. 5,041,100 issued August 20, 1991 ("Rowland '100").
50. U.S. Patent No. 5,076,265 issued December 31, 1991 ("Wokalek '265").
51. U.S. Patent No. 5,156,843 issued October 20, 1992 ("Leong '843").
52. U.S. Patent No. 5,166,187 issued November 24, 1992 ("Collombel '187").
53. U.S. Patent No. 5,324,775 issued June 28, 1994 ("Rhee '775").
54. U.S. Patent No. 5,370,681 issued December 6, 1994 ("Herweck '681").
55. U.S. Patent No. 5,425,953 issued June 20, 1995 ("Sintov '953").
56. U.S. Patent No. 5,457,093 issued October 10, 1995 ("Cini '093").
57. U.S. Patent No. 5,650,447 issued July 22, 1997 ("Keefer '447").
58. U.S. Patent No. 5,994,341 issued November 30, 1999 ("Hunter '341").

59. U.S. Patent No. 6,146,358 issued November 14, 2000 ("Rowe '358").
60. U.S. Patent No. 4,447,590 issued May 8, 1984 ("Szycher '590").
61. U.S. Patent No. 4,873,308 issued October 10, 1989 ("Coury '308").
62. U.S. Patent No. 4,886,06 issued December 12, 1989 ("Wiktor '062").
63. U.S. Patent No. 4,943,449 issued July 24, 1990 ("Aishima '449").
64. U.S. Patent No. 5,156,844 issued October 20, 1992 ("Aebischer '844").
65. U.S. Patent No. 5,405,99 issued April 11, 1995 ("Keefer '919").
66. U.S. Patent No. 5,466,262 issued November 14, 1995 ("Saffran '262").
67. U.S. Patent No. 5,525,357 issued June 11, 1996 ("Keefer '357").
68. U.S. Patent No. 4, 733,665 issued March 29, 1988 ("Palmaz '665").
69. U.S. Patent No. 4,739,762 issued April 26, 1988 ("Palmaz '762").
70. U.S. Patent No. 4,776,337 issued October 11, 2988 ("Palmaz '337").
71. U.S. Patent No. 3,948,254 issued April 6, 1976 ("Zaffaroni '254").
72. U.S. Patent No. 4,321,711 issued March 30, 1982 ("Mano '711").
73. U.S. Patent No. 4,391,797 issued July 5, 1983 ("Folkman '797").
74. U.S. Patent No. 4,613,665 issued September 23, 1986 ("Larm '665").
75. U.S. Patent No. 4,693,720 issued September 15, 1987 ("Scharnberg '720").
76. U.S. Patent No. 5,053,048 issued October 1, 1992 ("Pinchuk '048").
77. U.S. Patent No. 5,084,051 issued January 28, 1992 ("Tormala '051").
78. U.S. Patent No. 5,213,580 issued May 25, 1993 ("Slepian '580").
79. U.S. Patent No. 5,234,456 issued August 10, 1993 ("Silvestrini '456").
80. U.S. Patent No. 5,290,271 issued March 1, 1994 ("Jernberg '271").
81. U.S. Patent No. 5,304,121 issued April 19, 1994 ("Sahatjian '121").

82. U.S. Patent No. 5,464,650 issued November 7, 1995 ("Berg '650").
83. U.S. Patent No. 5,575,815 issued November 19, 1996 ("Slepian '815").
84. U.S. Patent No. 5,674,192 issued October 7, 1997 ("Sahatjian '192").
85. U.S. Patent No. 5,609,629 issued March 11, 1997 ("Fearnot '629").
86. U.S. Patent No. 5,624,411 issued April 29, 1997 ("Tuch '411").
87. U.S. Patent No. 5,725,567 issued March 10, 1998 ("Wolff '567").
88. European Patent Office Publication 0 335 341 B1 published March 4, 1992 ("Palmaz '341").
89. European Patent Office Publication 0 339 821 A1 published November 2, 1989 ("Chadwick '821").
90. European Patent Office Publication 0 449 592 A1 published October 2, 1991 ("Urry '592").
91. International Application WO 91/12779 published September 5, 1991 ("Wolff '779").
92. International Application WO 93/111120 published June 10, 1993 ("Kopia '120").
93. Langer, R. "Controlled Release: A New Approach to Drug Delivery." *Technology Review*, April 1981, 26-34. ("Langer I")
94. Langer, R. *New Drug Delivery Systems: What the Clinician Can Expect*. *Drug Therapy*, April 1983, 217-31. ("Langer II")
95. Langer, RS. *Long-Acting Contraceptive Delivery Systems*. Proceedings of an International Workshop on Long-Acting Contraceptive Delivery Systems, May 31-June 3, 1983, (Zatuchni, GI, et al., eds.), 23-32. ("Langer III")

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EXHIBIT B

The prior art patents listed as 35 U.S.C. § 102 references may also be combined with many other prior art references to be deemed effective 35 U.S.C. § 103 prior art as well. Additionally, the sets of prior art patents listed as 35 U.S.C. § 103 prior art combinations are illustrative only and there are many other combinations involving the each set of listed patents that are not illustrated.

The following list identifies exemplary prior art that anticipates or renders obvious the asserted claims of the '760 patents. Some references are listed as both anticipating and as rendering the claims obvious. To the extent the references are found to be not anticipating, the references, alone or in combination with another reference(s), alternatively render the claims obvious.

1. **Palmaz '417** anticipates. In addition, this art renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6-5-10; col. 23:6-36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4;

2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40; 30:49-53; 31:62-64; 36:21-62; 36:65-37:31; 37:34-48; 37:56-60; 37:63-38:23; 38:24-38; 38:47-60; 39:39-41; 40:33-34; 40:37-42; 49:27-31); Hunter '981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47; 7:12-16; Fig. 13; Fig. 14; Fig. 17E; 11:56-59; 12:23-46; 12:55-59; 12:64-13:37; 13:40-52; 13:54-14:67; 15:3-16:56; 16:66-17:26; 17:41-43; 17:63-18:7; 18:15-49; 22:3-7; 22:21-64; 23:6-13; 23:26-31; 23:46-51; 24:45-51; 24:66-25:5; 25:24-29; 25:48-54; 26:24-29; 44:60-45:31; 47:58-49:7; 52:4-8; 56:45-57; 57:17-31; 59:32-60:48; 66:13-22; 69:19-62; 77:43-55; 78:58-79:5; 84:62-86:24; 86:56-67; 87:11-22; 88:19-26; 87:1-2); Kowligi '782 (Abstract; Figs. 1-3; col. 1:18-64; 2:15-20; 2:38-3:4; 3:7-12; 3:27-38; col. 4:1-5; col. 4:16-39; 4:64-66; 5:4-7; 5:16-21; 7:49-8:9; 8:38-44; 9:65-10:6; 10:18-67); Lambert

'922 (Abstract; 1:46-55; 1:62-65; col. 2:16-35; 2:40-50; 2:55-67; 3:8-12; 3:15-61; 4:10-17; 5:56-6:34; 7:29-32; 7:38-41; 7:55-58; 8:1-6; 8:62-9:19; 9:31-37; 10:54-64; 11:49-56; 11:65-12:13; 12:21-22; 12:27-30; 12:40-64; 13:10-19); Lambert '308 (Abstract; p. 2:10-19; 2:25-30; 3:10-31; 4:2-12; 4:17-31; 5:15-28; 6:15-28; 10:17-11:15; 13:20-24; 15:25-16:14; p.16:27-34; claim 1:1-14; claim 8; claim 10:1-3; claim 11; claim 14; claim 16; claim 19:1-31; claim 20; claim 22; claim 23:1-14; claim 26; claim 27:1-5); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711 (Col. 2:44-3:6; 3:16-21; 3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 5:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21;

1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27;

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2. **Scott '928** anticipates. In addition, this art renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20;

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2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-

26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-40; 5:19-21; 5:32-34; 3:52-56; 5:65-6:2; 7:28-36; 8:17-22; 8:28-32; 8:67-9:8; 9:15-23; 9:24-32; 9:42-46); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor

'062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88);

Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

3. **Schwartz '823** anticipates. In addition, this art renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29;

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Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

4. **Aebischer '486** anticipates. In addition, this art renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-

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12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60;

6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-40; 5:19-21; 5:32-34; 3:52-56; 5:65-6:2; 7:28-36; 8:17-22; 8:28-32; 8:67-9:8; 9:15-23; 9:24-32; 9:42-46); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24);

Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

5. **Lambert '246, Lambert '922, and/or Lambert '308** anticipate. In addition, this art renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7;

4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40; 30:49-53; 31:62-64; 36:21-62; 36:65-37:31; 37:34-48; 37:56-60; 37:63-38:23; 38:24-38; 38:47-

60; 39:39-41; 40:33-34; 40:37-42; 49:27-31); Hunter '981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47; 7:12-16; Fig. 13; Fig. 14; Fig. 17E; 11:56-59; 12:23-46; 12:55-59; 12:64-13:37; 13:40-52; 13:54-14:67; 15:3-16:56; 16:66-17:26; 17:41-43; 17:63-18:7; 18:15-49; 22:3-7; 22:21-64; 23:6-13; 23:26-31; 23:46-51; 24:45-51; 24:66-25:5; 25:24-29; 25:48-54; 26:24-29; 44:60-45:31; 47:58-49:7; 52:4-8; 56:45-57; 57:17-31; 59:32-60:48; 66:13-22; 69:19-62; 77:43-55; 78:58-79:5; 84:62-86:24; 86:56-67; 87:11-22; 88:19-26; 87:1-2); Kowligi '782 (Abstract; Figs. 1-3; col. 1:18-64; 2:15-20; 2:38-3:4; 3:7-12; 3:27-38; col. 4:1-5; col. 4:16-39; 4:64-66; 5:4-7; 5:16-21; 7:49-8:9; 8:38-44; 9:65-10:6; 10:18-67); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711 (Col. 2:44-3:6; 3:16-21; 3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 50:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7;

2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19);

Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-40; 5:19-21; 5:32-34; 3:52-56; 5:65-6:2; 7:28-36; 8:17-22; 8:28-32; 8:67-9:8; 9:15-23; 9:24-32; 9:42-46); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650;

Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

6. **Tartgalia '113** anticipates. In addition, this art renders obvious by itself

and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40;

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9:42-46); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181,

1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

7. **Wolff '208** anticipates. In addition, this art renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-

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Mitchell '711 (Col. 2:44-3:6; 3:16-21; 3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 5:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col.

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17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

8. **Berg '354** anticipates. In addition, this art renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2;

2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65;
8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5;
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13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32;
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9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract;
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7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096
(Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-
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'981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47; 7:12-16; Fig. 13; Fig. 14; Fig. 17E; 11:56-59; 12:23-46;
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Kowligi '782 (Abstract; Figs. 1-3; col. 1:18-64; 2:15-20; 2:38-3:4; 3:7-12; 3:27-38; col. 4:1-5; col. 4:16-39; 4:64-66; 5:4-7; 5:16-21; 7:49-8:9; 8:38-44; 9:65-10:6; 10:18-67); Lambert '922 (Abstract; 1:46-55; 1:62-65; col. 2:16-35; 2:40-50; 2:55-67; 3:8-12; 3:15-61; 4:10-17; 5:56-6:34; 7:29-32; 7:38-41; 7:55-58; 8:1-6; 8:62-9:19; 9:31-37; 10:54-64; 11:49-56; 11:65-12:13; 12:21-22; 12:27-30; 12:40-64; 13:10-19); Lambert '308 (Abstract; p. 2:10-19; 2:25-30; 3:10-31; 4:2-12; 4:17-31; 5:15-28; 6:15-28; 10:17-11:15; 13:20-24; 15:25-16:14; p.16:27-34; claim 1:1-14; claim 8; claim 10:1-3; claim 11; claim 14; claim 16; claim 19:1-31; claim 20; claim 22; claim 23:1-14; claim 26; claim 27:1-5); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711 (Col. 2:44-3:6; 3:16-21; 3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 5:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7;

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Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-40; 5:19-21; 5:32-34; 3:52-56; 5:65-6:2; 7:28-36; 8:17-22; 8:28-32; 8:67-9:8; 9:15-23; 9:24-32; 9:42-46); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman

'797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

9. **Buscemi '450** anticipates. In addition, this art renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-

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'417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3;

9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-

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Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

10. **Hunter '981** anticipates. In addition, this art renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-

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12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 50:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20;

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Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39;
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349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

11. **Bellamkonda '029** anticipates. In addition, this art renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208

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87:11-22; 88:19-26; 87:1-2); Kowligi '782 (Abstract; Figs. 1-3; col. 1:18-64; 2:15-20; 2:38-3:4; 3:7-12; 3:27-38; col. 4:1-5; col. 4:16-39; 4:64-66; 5:4-7; 5:16-21; 7:49-8:9; 8:38-44; 9:65-10:6; 10:18-67); Lambert '922 (Abstract; 1:46-55; 1:62-65; col. 2:16-35; 2:40-50; 2:55-67; 3:8-12; 3:15-61; 4:10-17; 5:56-6:34; 7:29-32; 7:38-41; 7:55-58; 8:1-6; 8:62-9:19; 9:31-37; 10:54-64; 11:49-56; 11:65-12:13; 12:21-22; 12:27-30; 12:40-64; 13:10-19); Lambert '308 (Abstract; p. 2:10-19; 2:25-30; 3:10-31; 4:2-12; 4:17-31; 5:15-28; 6:15-28; 10:17-11:15; 13:20-24; 15:25-16:14; p.16:27-34; claim 1:1-14; claim 8; claim 10:1-3; claim 11; claim 14; claim 16; claim 19:1-31; claim 20; claim 22; claim 23:1-14; claim 26; claim 27:1-5); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711 (Col. 2:44-3:6; 3:16-21; 3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 5:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189

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7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-40; 5:19-21; 5:32-34; 3:52-56; 5:65-6:2; 7:28-36; 8:17-22; 8:28-32; 8:67-9:8; 9:15-23; 9:24-32; 9:42-46); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411;

Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

12. **Ding '536** anticipates. In addition, this art renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62;

1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40; 30:49-53; 31:62-64; 36:21-62; 36:65-37:31; 37:34-48; 37:56-60;

37:63-38:23; 38:24-38; 38:47-60; 39:39-41; 40:33-34; 40:37-42; 49:27-31); Hunter '981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47; 7:12-16; Fig. 13; Fig. 14; Fig. 17E; 11:56-59; 12:23-46; 12:55-59; 12:64-13:37; 13:40-52; 13:54-14:67; 15:3-16:56; 16:66-17:26; 17:41-43; 17:63-18:7; 18:15-49; 22:3-7; 22:21-64; 23:6-13; 23:26-31; 23:46-51; 24:45-51; 24:66-25:5; 25:24-29; 25:48-54; 26:24-29; 44:60-45:31; 47:58-49:7; 52:4-8; 56:45-57; 57:17-31; 59:32-60:48; 66:13-22; 69:19-62; 77:43-55; 78:58-79:5; 84:62-86:24; 86:56-67; 87:11-22; 88:19-26; 87:1-2); Kowligi '782 (Abstract; Figs. 1-3; col. 1:18-64; 2:15-20; 2:38-3:4; 3:7-12; 3:27-38; col. 4:1-5; col. 4:16-39; 4:64-66; 5:4-7; 5:16-21; 7:49-8:9; 8:38-44; 9:65-10:6; 10:18-67); Lambert '922 (Abstract; 1:46-55; 1:62-65; col. 2:16-35; 2:40-50; 2:55-67; 3:8-12; 3:15-61; 4:10-17; 5:56-6:34; 7:29-32; 7:38-41; 7:55-58; 8:1-6; 8:62-9:19; 9:31-37; 10:54-64; 11:49-56; 11:65-12:13; 12:21-22; 12:27-30; 12:40-64; 13:10-19); Lambert '308 (Abstract; p. 2:10-19; 2:25-30; 3:10-31; 4:2-12; 4:17-31; 5:15-28; 6:15-28; 10:17-11:15; 13:20-24; 15:25-16:14; p.16:27-34; claim 1:1-14; claim 8; claim 10:1-3; claim 11; claim 14; claim 16; claim 19:1-31; claim 20; claim 22; claim 23:1-14; claim 26; claim 27:1-5); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711 (Col. 2:44-3:6; 3:16-21; 3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 50:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-

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17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-40; 5:19-21; 5:32-34; 3:52-56; 5:65-6:2; 7:28-36; 8:17-22; 8:28-32; 8:67-9:8; 9:15-23; 9:24-32; 9:42-46); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-

53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263,

266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

13. **Dinh '227** anticipates. In addition, this art renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9;

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176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

14. **Domb '055** anticipates. In addition, this art renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract;

Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40; 30:49-53; 31:62-64; 36:21-62; 36:65-37:31; 37:34-48; 37:56-60; 37:63-38:23; 38:24-38; 38:47-60; 39:39-41; 40:33-34; 40:37-42; 49:27-31); Hunter '981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47; 7:12-16; Fig. 13; Fig. 14; Fig. 17E; 11:56-59; 12:23-46; 12:55-59; 12:64-13:37; 13:40-52; 13:54-14:67; 15:3-16:56; 16:66-17:26; 17:41-43; 17:63-18:7; 18:15-49; 22:3-7; 22:21-64; 23:6-13; 23:26-31; 23:46-51; 24:45-51; 24:66-25:5; 25:24-29; 25:48-54; 26:24-29; 44:60-45:31; 47:58-49:7; 52:4-8; 56:45-57; 57:17-31; 59:32-60:48; 66:13-22; 69:19-62; 77:43-55; 78:58-79:5; 84:62-86:24; 86:56-67; 87:11-22; 88:19-26; 87:1-2); Kowligi '782 (Abstract; Figs. 1-3; col. 1:18-64; 2:15-20; 2:38-3:4; 3:7-12; 3:27-38; col. 4:1-5; col. 4:16-39; 4:64-66; 5:4-7; 5:16-21; 7:49-8:9; 8:38-44; 9:65-10:6; 10:18-67); Lambert '922

(Abstract; 1:46-55; 1:62-65; col. 2:16-35; 2:40-50; 2:55-67; 3:8-12; 3:15-61; 4:10-17; 5:56-6:34; 7:29-32; 7:38-41; 7:55-58; 8:1-6; 8:62-9:19; 9:31-37; 10:54-64; 11:49-56; 11:65-12:13; 12:21-22; 12:27-30; 12:40-64; 13:10-19); Lambert '308 (Abstract; p. 2:10-19; 2:25-30; 3:10-31; 4:2-12; 4:17-31; 5:15-28; 6:15-28; 10:17-11:15; 13:20-24; 15:25-16:14; p.16:27-34; claim 1:1-14; claim 8; claim 10:1-3; claim 11; claim 14; claim 16; claim 19:1-31; claim 20; claim 22; claim 23:1-14; claim 26; claim 27:1-5); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711 (Col. 2:44-3:6; 3:16-21; 3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 5:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col.

2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-

57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-40; 5:19-21; 5:32-34; 3:52-56; 5:65-6:2; 7:28-36; 8:17-22; 8:28-32; 8:67-9:8; 9:15-23; 9:24-32; 9:42-46); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411;

Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

15. **Myler '563** anticipates. In addition, this art renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-

62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6-5:10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-

32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40; 30:49-53; 31:62-64; 36:21-62; 36:65-37:31; 37:34-48; 37:56-60; 37:63-38:23; 38:24-38; 38:47-60; 39:39-41; 40:33-34; 40:37-42; 49:27-31); Hunter '981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47; 7:12-16; Fig. 13; Fig. 14; Fig. 17E; 11:56-59; 12:23-46; 12:55-59; 12:64-13:37; 13:40-52; 13:54-14:67; 15:3-16:56; 16:66-17:26; 17:41-43; 17:63-18:7; 18:15-49; 22:3-7; 22:21-64; 23:6-13; 23:26-31; 23:46-51; 24:45-51; 24:66-25:5; 25:24-29; 25:48-54; 26:24-29; 44:60-45:31; 47:58-49:7; 52:4-8; 56:45-57; 57:17-31; 59:32-60:48; 66:13-22; 69:19-62; 77:43-55; 78:58-79:5; 84:62-86:24; 86:56-67; 87:11-22; 88:19-26; 87:1-2); Kowligi '782 (Abstract; Figs. 1-3; col. 1:18-64; 2:15-20; 2:38-3:4; 3:7-12; 3:27-38; col. 4:1-5; col. 4:16-39; 4:64-66; 5:4-7; 5:16-21; 7:49-8:9; 8:38-44; 9:65-10:6; 10:18-67); Lambert '922 (Abstract; 1:46-55; 1:62-65; col. 2:16-35; 2:40-50; 2:55-67; 3:8-12; 3:15-61; 4:10-17; 5:56-6:34; 7:29-32; 7:38-41; 7:55-58; 8:1-6; 8:62-9:19; 9:31-37; 10:54-64; 11:49-56; 11:65-12:13; 12:21-22; 12:27-30; 12:40-64; 13:10-19); Lambert '308 (Abstract; p. 2:10-19; 2:25-30; 3:10-31; 4:2-12; 4:17-31; 5:15-28; 6:15-28; 10:17-11:15; 13:20-24; 15:25-16:14; p.16:27-34; claim 1:1-14; claim 8; claim 10:1-3; claim 11; claim 14; claim 16; claim 19:1-31; claim 20; claim 22; claim 23:1-14; claim 26; claim 27:1-5); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711 (Col. 2:44-3:6; 3:16-21; 3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330

(Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2;

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Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages

166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

16. **Schiraldi '243** anticipates. In addition, this art renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-

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8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 50:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col.

8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32:26-31); Palmaz '665 (Abstract; Figs.

1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-40; 5:19-21; 5:32-34; 3:52-56; 5:65-6:2; 7:28-36; 8:17-22; 8:28-32; 8:67-9:8; 9:15-23; 9:24-32; 9:42-46); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74,

176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

17. **Wood '066** anticipates. In addition, this art renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract;

Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40; 30:49-53; 31:62-64; 36:21-62; 36:65-37:31; 37:34-48; 37:56-60; 37:63-38:23; 38:24-38; 38:47-60; 39:39-41; 40:33-34; 40:37-42; 49:27-31); Hunter '981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47; 7:12-16; Fig. 13; Fig. 14; Fig. 17E; 11:56-59; 12:23-46; 12:55-59; 12:64-13:37; 13:40-52; 13:54-14:67; 15:3-16:56; 16:66-17:26; 17:41-43; 17:63-18:7; 18:15-49; 22:3-7; 22:21-64; 23:6-13; 23:26-31; 23:46-51; 24:45-51; 24:66-25:5; 25:24-29; 25:48-54; 26:24-29; 44:60-45:31; 47:58-49:7; 52:4-8; 56:45-57; 57:17-31; 59:32-60:48; 66:13-22; 69:19-62; 77:43-55; 78:58-79:5; 84:62-86:24; 86:56-67; 87:11-22; 88:19-26;

87:1-2); Kowligi '782 (Abstract; Figs. 1-3; col. 1:18-64; 2:15-20; 2:38-3:4; 3:7-12; 3:27-38; col. 4:1-5; col. 4:16-39; 4:64-66; 5:4-7; 5:16-21; 7:49-8:9; 8:38-44; 9:65-10:6; 10:18-67); Lambert '922 (Abstract; 1:46-55; 1:62-65; col. 2:16-35; 2:40-50; 2:55-67; 3:8-12; 3:15-61; 4:10-17; 5:56-6:34; 7:29-32; 7:38-41; 7:55-58; 8:1-6; 8:62-9:19; 9:31-37; 10:54-64; 11:49-56; 11:65-12:13; 12:21-22; 12:27-30; 12:40-64; 13:10-19); Lambert '308 (Abstract; p. 2:10-19; 2:25-30; 3:10-31; 4:2-12; 4:17-31; 5:15-28; 6:15-28; 10:17-11:15; 13:20-24; 15:25-16:14; p.16:27-34; claim 1:1-14; claim 8; claim 10:1-3; claim 11; claim 14; claim 16; claim 19:1-31; claim 20; claim 22; claim 23:1-14; claim 26; claim 27:1-5); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711 (Col. 2:44-3:6; 3:16-21; 3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 5:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7;

2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54);

Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-40; 5:19-21; 5:32-34; 3:52-56; 5:65-6:2; 7:28-36; 8:17-22; 8:28-32; 8:67-9:8; 9:15-23; 9:24-32; 9:42-46); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650;

Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

18. **Strecker '746** anticipates. In addition, this art renders obvious by itself

and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6-5:10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42);

Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40; 30:49-53; 31:62-64; 36:21-62; 36:65-37:31; 37:34-48; 37:56-60; 37:63-38:23; 38:24-38; 38:47-60; 39:39-41; 40:33-34; 40:37-42; 49:27-31); Hunter '981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47; 7:12-16; Fig. 13; Fig. 14; Fig. 17E; 11:56-59; 12:23-46; 12:55-59; 12:64-13:37; 13:40-52; 13:54-14:67; 15:3-16:56; 16:66-17:26; 17:41-43; 17:63-18:7; 18:15-49; 22:3-7; 22:21-64; 23:6-13; 23:26-31; 23:46-51; 24:45-51; 24:66-25:5; 25:24-29; 25:48-54; 26:24-29; 44:60-45:31; 47:58-49:7; 52:4-8; 56:45-57; 57:17-31; 59:32-60:48; 66:13-22; 69:19-62; 77:43-55; 78:58-79:5; 84:62-86:24; 86:56-67; 87:11-22; 88:19-26; 87:1-2); Kowligi '782 (Abstract; Figs. 1-3; col. 1:18-64; 2:15-20; 2:38-3:4; 3:7-12; 3:27-38; col. 4:1-5; col. 4:16-39; 4:64-66; 5:4-7; 5:16-21; 7:49-8:9; 8:38-44; 9:65-10:6; 10:18-67); Lambert '922 (Abstract; 1:46-55; 1:62-65; col. 2:16-35; 2:40-50; 2:55-67; 3:8-12; 3:15-61; 4:10-17; 5:56-6:34; 7:29-32; 7:38-41; 7:55-58; 8:1-6; 8:62-9:19; 9:31-37; 10:54-64; 11:49-56; 11:65-12:13; 12:21-22; 12:27-30; 12:40-64; 13:10-19); Lambert '308 (Abstract; p. 2:10-19; 2:25-30; 3:10-31; 4:2-12; 4:17-31; 5:15-28; 6:15-28; 10:17-11:15; 13:20-24; 15:25-16:14; p.16:27-34; claim 1:1-14; claim 8; claim 10:1-3; claim 11; claim 14; claim 16; claim 19:1-31; claim 20; claim 22; claim 23:1-14; claim 26; claim 27:1-5); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711 (Col. 2:44-3:6; 3:16-21; 3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 50:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13;

12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-

6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-40; 5:19-21; 5:32-34; 3:52-56; 5:65-6:2; 7:28-36; 8:17-22; 8:28-32; 8:67-9:8; 9:15-23; 9:24-32;

9:42-46); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181,

1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

19. **Burt '036** anticipates. In addition, this art renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29;

7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40; 30:49-53; 31:62-64; 36:21-62; 36:65-37:31; 37:34-48; 37:56-60; 37:63-38:23; 38:24-38; 38:47-60; 39:39-41; 40:33-34; 40:37-42; 49:27-31); Hunter '981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47; 7:12-16; Fig. 13; Fig. 14; Fig. 17E; 11:56-59; 12:23-46; 12:55-59; 12:64-13:37; 13:40-52; 13:54-14:67; 15:3-16:56; 16:66-17:26; 17:41-43; 17:63-18:7; 18:15-49; 22:3-7; 22:21-64; 23:6-13; 23:26-31; 23:46-51; 24:45-51; 24:66-25:5; 25:24-29; 25:48-54; 26:24-29; 44:60-45:31; 47:58-49:7; 52:4-8; 56:45-57; 57:17-31; 59:32-60:48; 66:13-22; 69:19-62; 77:43-55; 78:58-79:5; 84:62-86:24; 86:56-67; 87:11-22; 88:19-26; 87:1-2); Kowligi '782 (Abstract; Figs. 1-3; col. 1:18-64; 2:15-20; 2:38-3:4; 3:7-12; 3:27-38; col. 4:1-5; col. 4:16-39; 4:64-66; 5:4-7; 5:16-21; 7:49-8:9; 8:38-44; 9:65-10:6; 10:18-67); Lambert '922 (Abstract; 1:46-55; 1:62-65; col. 2:16-35; 2:40-50; 2:55-67; 3:8-12; 3:15-61; 4:10-17; 5:56-6:34; 7:29-32; 7:38-41; 7:55-58; 8:1-6; 8:62-9:19; 9:31-37; 10:54-64; 11:49-56; 11:65-12:13; 12:21-22; 12:27-30; 12:40-64; 13:10-19); Lambert '308 (Abstract; p. 2:10-19; 2:25-30; 3:10-31; 4:2-12; 4:17-31; 5:15-28; 6:15-28; 10:17-11:15; 13:20-24; 15:25-16:14; p.16:27-34; claim 1:1-14; claim

8; claim 10:1-3; claim 11; claim 14; claim 16; claim 19:1-31; claim 20; claim 22; claim 23:1-14; claim 26; claim 27:1-5); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711 (Col. 2:44-3:6; 3:16-21; 3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 50:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21;

1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41;

1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-40; 5:19-21; 5:32-34; 3:52-56; 5:65-6:2; 7:28-36; 8:17-22; 8:28-32; 8:67-9:8; 9:15-23; 9:24-32; 9:42-46); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-

649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102. 105. 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

20. **Goldin '568** anticipates. In addition, this art renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7;

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21. **Palmaz '762** anticipates. In addition, this art renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-

20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40; 30:49-53; 31:62-64; 36:21-62; 36:65-37:31; 37:34-48; 37:56-60; 37:63-38:23; 38:24-38; 38:47-60; 39:39-41; 40:33-34; 40:37-42; 49:27-31); Hunter '981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47; 7:12-16; Fig. 13; Fig. 14; Fig. 17E; 11:56-59; 12:23-46; 12:55-59; 12:64-13:37; 13:40-52; 13:54-14:67; 15:3-16:56; 16:66-17:26; 17:41-43; 17:63-18:7; 18:15-49; 22:3-7; 22:21-64; 23:6-13; 23:26-31; 23:46-51; 24:45-51; 24:66-25:5; 25:24-29; 25:48-54; 26:24-29; 44:60-45:31; 47:58-49:7; 52:4-8; 56:45-57; 57:17-31; 59:32-60:48; 66:13-22; 69:19-62; 77:43-55; 78:58-79:5; 84:62-86:24; 86:56-67; 87:11-22; 88:19-26; 87:1-2); Kowligi '782 (Abstract; Figs. 1-3; col. 1:18-64; 2:15-20; 2:38-3:4; 3:7-12; 3:27-38; col. 4:1-5; col. 4:16-39; 4:64-66; 5:4-7; 5:16-21; 7:49-8:9; 8:38-44; 9:65-10:6; 10:18-67); Lambert '922 (Abstract; 1:46-55; 1:62-65; col. 2:16-35; 2:40-50; 2:55-67; 3:8-12; 3:15-61; 4:10-17; 5:56-6:34; 7:29-32; 7:38-41; 7:55-58; 8:1-6; 8:62-9:19; 9:31-37; 10:54-64; 11:49-56; 11:65-12:13; 12:21-22; 12:27-30; 12:40-64; 13:10-19); Lambert '308 (Abstract; p. 2:10-19; 2:25-30; 3:10-31; 4:2-12; 4:17-31; 5:15-28; 6:15-28; 10:17-11:15; 13:20-24; 15:25-16:14; p.16:27-34; claim 1:1-14; claim 8; claim 10:1-3; claim 11; claim 14; claim 16; claim 19:1-31; claim 20; claim 22; claim 23:1-14; claim 26; claim 27:1-5); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711 (Col. 2:44-3:6; 3:16-21; 3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67;

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349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn
(pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee &
Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer &
Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman
III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286;

Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

22. **Palmaz '337** anticipates. In addition, this art renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-

25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40; 30:49-53; 31:62-64; 36:21-62; 36:65-37:31; 37:34-48; 37:56-60; 37:63-38:23; 38:24-38; 38:47-60; 39:39-41; 40:33-34; 40:37-42; 49:27-31); Hunter '981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47; 7:12-16; Fig. 13; Fig. 14; Fig. 17E; 11:56-59; 12:23-46; 12:55-59; 12:64-13:37; 13:40-52; 13:54-14:67; 15:3-16:56; 16:66-17:26; 17:41-43; 17:63-18:7; 18:15-49; 22:3-7; 22:21-64; 23:6-13; 23:26-31; 23:46-51; 24:45-51; 24:66-25:5; 25:24-29; 25:48-54; 26:24-29; 44:60-45:31; 47:58-49:7; 52:4-8; 56:45-57; 57:17-31; 59:32-60:48; 66:13-22; 69:19-62; 77:43-55; 78:58-79:5; 84:62-86:24; 86:56-67; 87:11-22; 88:19-26; 87:1-2); Kowligi '782 (Abstract; Figs. 1-3; col. 1:18-64; 2:15-20; 2:38-3:4; 3:7-12; 3:27-38; col. 4:1-5; col. 4:16-39; 4:64-66; 5:4-7; 5:16-21; 7:49-8:9; 8:38-44; 9:65-10:6; 10:18-67); Lambert '922 (Abstract; 1:46-55; 1:62-65; col. 2:16-35; 2:40-50; 2:55-67; 3:8-12; 3:15-61; 4:10-17; 5:56-6:34; 7:29-32; 7:38-41; 7:55-58; 8:1-6; 8:62-9:19; 9:31-37; 10:54-64; 11:49-56; 11:65-12:13; 12:21-22; 12:27-30; 12:40-64; 13:10-19); Lambert '308 (Abstract; p. 2:10-19; 2:25-30; 3:10-31;

4:2-12; 4:17-31; 5:15-28; 6:15-28; 10:17-11:15; 13:20-24; 15:25-16:14; p.16:27-34; claim 1:1-14; claim 8; claim 10:1-3; claim 11; claim 14; claim 16; claim 19:1-31; claim 20; claim 22; claim 23:1-14; claim 26; claim 27:1-5); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711 (Col. 2:44-3:6; 3:16-21; 3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 5:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-

66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66;

8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32:26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-

649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102. 105. 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

23. **Peterson '166** renders obvious in combination with one or more of Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-

67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40; 30:49-53; 31:62-64; 36:21-62; 36:65-37:31; 37:34-48; 37:56-60; 37:63-38:23; 38:24-38; 38:47-60; 39:39-41; 40:33-34; 40:37-42; 49:27-31); Hunter '981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47; 7:12-16; Fig. 13; Fig. 14; Fig. 17E; 11:56-59; 12:23-46; 12:55-59; 12:64-13:37; 13:40-52; 13:54-14:67; 15:3-16:56; 16:66-17:26; 17:41-43; 17:63-18:7; 18:15-49; 22:3-7; 22:21-64; 23:6-13; 23:26-31; 23:46-51; 24:45-51; 24:66-25:5; 25:24-29; 25:48-54; 26:24-29; 44:60-45:31; 47:58-49:7; 52:4-8; 56:45-57; 57:17-31; 59:32-60:48; 66:13-22; 69:19-62; 77:43-55;

78:58-79:5; 84:62-86:24; 86:56-67; 87:11-22; 88:19-26; 87:1-2); Kowligi '782 (Abstract; Figs. 1-3; col. 1:18-64; 2:15-20; 2:38-3:4; 3:7-12; 3:27-38; col. 4:1-5; col. 4:16-39; 4:64-66; 5:4-7; 5:16-21; 7:49-8:9; 8:38-44; 9:65-10:6; 10:18-67); Lambert '922 (Abstract; 1:46-55; 1:62-65; col. 2:16-35; 2:40-50; 2:55-67; 3:8-12; 3:15-61; 4:10-17; 5:56-6:34; 7:29-32; 7:38-41; 7:55-58; 8:1-6; 8:62-9:19; 9:31-37; 10:54-64; 11:49-56; 11:65-12:13; 12:21-22; 12:27-30; 12:40-64; 13:10-19); Lambert '308 (Abstract; p. 2:10-19; 2:25-30; 3:10-31; 4:2-12; 4:17-31; 5:15-28; 6:15-28; 10:17-11:15; 13:20-24; 15:25-16:14; p.16:27-34; claim 1:1-14; claim 8; claim 10:1-3; claim 11; claim 14; claim 16; claim 19:1-31; claim 20; claim 22; claim 23:1-14; claim 26; claim 27:1-5); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711 (Col. 2:44-3:6; 3:16-21; 3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 50:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-

39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 3:38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col. 3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55;

6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-40; 5:19-21; 5:32-34; 3:52-56; 5:65-6:2; 7:28-36; 8:17-22; 8:28-32; 8:67-9:8; 9:15-23; 9:24-32; 9:42-46); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col.

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Aebischer IV (pages 599-600).

24. **Fox '096** renders obvious in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-

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 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12;
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1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

25. **Kowligi '782** renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30);

Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40; 30:49-53; 31:62-64; 36:21-62; 36:65-37:31; 37:34-48; 37:56-60; 37:63-38:23; 38:24-38; 38:47-60; 39:39-41; 40:33-34; 40:37-42; 49:27-31); Hunter '981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47; 7:12-16; Fig. 13; Fig. 14; Fig. 17E; 11:56-59; 12:23-46; 12:55-59; 12:64-13:37; 13:40-52; 13:54-14:67; 15:3-16:56; 16:66-17:26; 17:41-43; 17:63-18:7; 18:15-49; 22:3-7; 22:21-64; 23:6-13; 23:26-31; 23:46-51; 24:45-51; 24:66-25:5; 25:24-29; 25:48-54; 26:24-29; 44:60-45:31; 47:58-49:7; 52:4-8; 56:45-57; 57:17-31; 59:32-60:48; 66:13-22; 69:19-62; 77:43-55; 78:58-79:5; 84:62-86:24; 86:56-67; 87:11-22; 88:19-26; 87:1-2); Lambert '922 (Abstract; 1:46-55; 1:62-65; col. 2:16-35; 2:40-50; 2:55-67; 3:8-12; 3:15-61; 4:10-17; 5:56-6:34; 7:29-32; 7:38-41; 7:55-58; 8:1-6; 8:62-9:19; 9:31-37; 10:54-64; 11:49-56; 11:65-12:13; 12:21-22; 12:27-30; 12:40-64; 13:10-19); Lambert '308 (Abstract; p. 2:10-19; 2:25-30; 3:10-31; 4:2-12; 4:17-31; 5:15-28; 6:15-28; 10:17-11:15; 13:20-24; 15:25-16:14; p.16:27-34; claim 1:1-14; claim 8; claim 10:1-3; claim 11; claim 14; claim 16; claim 19:1-31; claim 20; claim 22; claim 23:1-14; claim 26; claim 27:1-5); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711

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Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

26. **Lambert '308** renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55;

3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40; 30:49-53; 31:62-64; 36:21-62; 36:65-37:31; 37:34-48; 37:56-60; 37:63-38:23; 38:24-38; 38:47-60; 39:39-41; 40:33-34; 40:37-42; 49:27-31); Hunter '981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47; 7:12-16; Fig. 13; Fig. 14; Fig. 17E; 11:56-59; 12:23-46; 12:55-59; 12:64-13:37; 13:40-52; 13:54-14:67; 15:3-16:56; 16:66-17:26; 17:41-43; 17:63-18:7; 18:15-49; 22:3-7; 22:21-64; 23:6-13; 23:26-31; 23:46-51; 24:45-51; 24:66-25:5; 25:24-29; 25:48-54; 26:24-29; 44:60-

45:31; 47:58-49:7; 52:4-8; 56:45-57; 57:17-31; 59:32-60:48; 66:13-22; 69:19-62; 77:43-55;
78:58-79:5; 84:62-86:24; 86:56-67; 87:11-22; 88:19-26; 87:1-2); Kowligi '782 (Abstract; Figs. 1-
3; col. 1:18-64; 2:15-20; 2:38-3:4; 3:7-12; 3:27-38; col. 4:1-5; col. 4:16-39; 4:64-66; 5:4-7; 5:16-
21; 7:49-8:9; 8:38-44; 9:65-10:6; 10:18-67); Lambert '922 (Abstract; 1:46-55; 1:62-65; col. 2:16-
35; 2:40-50; 2:55-67; 3:8-12; 3:15-61; 4:10-17; 5:56-6:34; 7:29-32; 7:38-41; 7:55-58; 8:1-6;
8:62-9:19; 9:31-37; 10:54-64; 11:49-56; 11:65-12:13; 12:21-22; 12:27-30; 12:40-64; 13:10-19);
WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711 (Col. 2:44-3:6;
3:16-21; 3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781
(col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42);
Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col.
8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15;
3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 50:50-
54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1;
13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13);
Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20;
5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38;
12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40;
15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-
68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40;
13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34;
2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16;
32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12;
11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-

41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda

'029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-40; 5:19-21; 5:32-34; 3:52-56; 5:65-6:2; 7:28-36; 8:17-22; 8:28-32; 8:67-9:8; 9:15-23; 9:24-32; 9:42-46); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650;

Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

27. **WO 94/21309** renders obvious by itself and/or in combination with one or

more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5;

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20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-

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28. **Mitchell '711** renders obvious in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44;

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13:20-24; 15:25-16:14; p.16:27-34; claim 1:1-14; claim 8; claim 10:1-3; claim 11; claim 14; claim 16; claim 19:1-31; claim 20; claim 22; claim 23:1-14; claim 26; claim 27:1-5); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 5:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-

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'568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-40; 5:19-21; 5:32-34; 3:52-56; 5:65-6:2; 7:28-36; 8:17-22; 8:28-32; 8:67-9:8; 9:15-23; 9:24-32; 9:42-46); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages

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29. **Morris '781** renders obvious in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113

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Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev

(Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

30. **Morris '182** renders obvious in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-

36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40; 30:49-53; 31:62-64; 36:21-62; 36:65-37:31; 37:34-48; 37:56-60; 37:63-38:23; 38:24-38; 38:47-60; 39:39-41; 40:33-34; 40:37-42; 49:27-31); Hunter '981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47; 7:12-16; Fig. 13; Fig. 14; Fig. 17E; 11:56-59; 12:23-46; 12:55-59; 12:64-13:37; 13:40-52; 13:54-14:67; 15:3-16:56; 16:66-17:26; 17:41-43; 17:63-18:7; 18:15-49; 22:3-7; 22:21-64; 23:6-13; 23:26-31; 23:46-51; 24:45-51; 24:66-25:5; 25:24-29; 25:48-54; 26:24-29; 44:60-45:31; 47:58-49:7; 52:4-8; 56:45-57; 57:17-31; 59:32-60:48; 66:13-22; 69:19-62; 77:43-55; 78:58-79:5; 84:62-86:24; 86:56-67; 87:11-22; 88:19-26; 87:1-2); Kowligi '782 (Abstract; Figs. 1-3; col. 1:18-64; 2:15-20; 2:38-3:4; 3:7-12; 3:27-38; col. 4:1-5; col. 4:16-39; 4:64-66; 5:4-7; 5:16-21; 7:49-8:9; 8:38-44; 9:65-10:6; 10:18-67); Lambert '922 (Abstract; 1:46-55; 1:62-65; col. 2:16-35; 2:40-50; 2:55-67; 3:8-12; 3:15-61; 4:10-17; 5:56-6:34; 7:29-32; 7:38-41; 7:55-58; 8:1-6; 8:62-9:19; 9:31-37; 10:54-64; 11:49-56; 11:65-12:13; 12:21-22; 12:27-30; 12:40-64; 13:10-19); Lambert '308 (Abstract; p. 2:10-19; 2:25-30; 3:10-31; 4:2-12; 4:17-31; 5:15-28; 6:15-28; 10:17-11:15; 13:20-24; 15:25-16:14; p.16:27-34; claim 1:1-14; claim 8; claim 10:1-3; claim 11; claim 14; claim 16; claim 19:1-31; claim 20; claim 22; claim 23:1-14; claim 26; claim 27:1-5); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711 (Col. 2:44-3:6; 3:16-21; 3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 50:50-54; 6:18-23; 10:12-

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2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-

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Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

31. **Tice '330** renders obvious in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17;

2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40; 30:49-53; 31:62-64; 36:21-62; 36:65-37:31; 37:34-48; 37:56-60; 37:63-38:23; 38:24-38; 38:47-60; 39:39-41; 40:33-34; 40:37-42; 49:27-31); Hunter '981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47; 7:12-16; Fig. 13; Fig. 14; Fig. 17E; 11:56-59; 12:23-46; 12:55-59; 12:64-13:37; 13:40-52; 13:54-14:67; 15:3-16:56; 16:66-17:26; 17:41-43; 17:63-18:7; 18:15-49; 22:3-7; 22:21-64; 23:6-13; 23:26-31; 23:46-51; 24:45-51; 24:66-25:5; 25:24-29; 25:48-54; 26:24-29; 44:60-45:31; 47:58-49:7; 52:4-8; 56:45-57; 57:17-31; 59:32-60:48; 66:13-22; 69:19-62; 77:43-55; 78:58-79:5; 84:62-86:24; 86:56-67; 87:11-22; 88:19-26; 87:1-2); Kowligi '782 (Abstract; Figs. 1-3; col. 1:18-64; 2:15-20; 2:38-3:4; 3:7-12; 3:27-38; col. 4:1-5; col. 4:16-39; 4:64-66; 5:4-7; 5:16-21; 7:49-8:9; 8:38-44; 9:65-10:6; 10:18-67); Lambert '922 (Abstract; 1:46-55; 1:62-65; col. 2:16-35; 2:40-50; 2:55-67; 3:8-12; 3:15-61; 4:10-17; 5:56-6:34; 7:29-32; 7:38-41; 7:55-58; 8:1-6; 8:62-9:19; 9:31-37; 10:54-64; 11:49-56; 11:65-12:13; 12:21-22; 12:27-30; 12:40-64; 13:10-19); Lambert

'308 (Abstract; p. 2:10-19; 2:25-30; 3:10-31; 4:2-12; 4:17-31; 5:15-28; 6:15-28; 10:17-11:15; 13:20-24; 15:25-16:14; p.16:27-34; claim 1:1-14; claim 8; claim 10:1-3; claim 11; claim 14; claim 16; claim 19:1-31; claim 20; claim 22; claim 23:1-14; claim 26; claim 27:1-5); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711 (Col. 2:44-3:6; 3:16-21; 3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 5:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496

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304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

32. **Thies '317** renders obvious in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47);

Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40; 30:49-53; 31:62-64; 36:21-62; 36:65-37:31; 37:34-48; 37:56-60; 37:63-38:23; 38:24-38; 38:47-60; 39:39-41; 40:33-34; 40:37-42; 49:27-31); Hunter '981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47;

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Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-

6); Langer XV (pages 102. 105. 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

33. **Tice '840** renders obvious in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51;

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'182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 50:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col.

20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-

11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-40; 5:19-21; 5:32-34; 3:52-56; 5:65-6:2; 7:28-36; 8:17-22; 8:28-32; 8:67-9:8; 9:15-23; 9:24-32; 9:42-46); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee &

Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

34. **Lapka '244** renders obvious in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-

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1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-

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101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

35. **Kent '189** renders obvious in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823

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36. **Tice '268** renders obvious in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38);

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19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

37. **Folkman '560** renders obvious in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-

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18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-

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Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

38. **Cohen '496** renders obvious in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62;

6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-

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'417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-

44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-40; 5:19-21; 5:32-34; 3:52-56; 5:65-6:2; 7:28-36; 8:17-22; 8:28-32; 8:67-9:8; 9:15-23; 9:24-32;

9:42-46); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181,

1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

39. **Helwing '868** renders obvious in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding

'536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40; 30:49-53; 31:62-64; 36:21-62; 36:65-37:31; 37:34-48; 37:56-60; 37:63-38:23; 38:24-38; 38:47-60; 39:39-41; 40:33-34; 40:37-42; 49:27-31); Hunter '981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47; 7:12-16; Fig. 13; Fig. 14; Fig. 17E; 11:56-59; 12:23-46; 12:55-59; 12:64-13:37; 13:40-52; 13:54-14:67; 15:3-16:56; 16:66-17:26; 17:41-43; 17:63-18:7; 18:15-49; 22:3-7; 22:21-64; 23:6-13; 23:26-31; 23:46-51; 24:45-51; 24:66-25:5; 25:24-29; 25:48-54; 26:24-29; 44:60-45:31; 47:58-49:7; 52:4-8; 56:45-57; 57:17-31; 59:32-60:48; 66:13-22; 69:19-62; 77:43-55; 78:58-79:5; 84:62-86:24; 86:56-67; 87:11-22; 88:19-26; 87:1-2); Kowligi '782 (Abstract; Figs. 1-3; col. 1:18-64; 2:15-20; 2:38-3:4; 3:7-12; 3:27-38; col. 4:1-5; col. 4:16-39; 4:64-66; 5:4-7; 5:16-21; 7:49-8:9; 8:38-44; 9:65-10:6; 10:18-67); Lambert '922 (Abstract; 1:46-55; 1:62-65; col. 2:16-35; 2:40-50; 2:55-67; 3:8-12; 3:15-61; 4:10-17; 5:56-6:34; 7:29-32; 7:38-41; 7:55-58; 8:1-6; 8:62-9:19; 9:31-37; 10:54-64; 11:49-56; 11:65-12:13; 12:21-22; 12:27-30; 12:40-64; 13:10-19); Lambert '308 (Abstract; p. 2:10-19; 2:25-30; 3:10-31; 4:2-12; 4:17-31; 5:15-28; 6:15-28; 10:17-11:15; 13:20-24; 15:25-16:14; p.16:27-34; claim 1:1-14; claim 8; claim 10:1-3; claim 11; claim 14;

claim 16; claim 19:1-31; claim 20; claim 22; claim 23:1-14; claim 26; claim 27:1-5); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711 (Col. 2:44-3:6; 3:16-21; 3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 5:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12;

4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37;

3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-40; 5:19-21; 5:32-34; 3:52-56; 5:65-6:2; 7:28-36; 8:17-22; 8:28-32; 8:67-9:8; 9:15-23; 9:24-32; 9:42-46); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer &

Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

40. **Valentini '029** renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6-5-10; col. 23:6-36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19;

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Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

41. **Greco '135** renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-

68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40; 30:49-53; 31:62-64; 36:21-62; 36:65-37:31; 37:34-48; 37:56-60; 37:63-38:23; 38:24-

38; 38:47-60; 39:39-41; 40:33-34; 40:37-42; 49:27-31); Hunter '981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47; 7:12-16; Fig. 13; Fig. 14; Fig. 17E; 11:56-59; 12:23-46; 12:55-59; 12:64-13:37; 13:40-52; 13:54-14:67; 15:3-16:56; 16:66-17:26; 17:41-43; 17:63-18:7; 18:15-49; 22:3-7; 22:21-64; 23:6-13; 23:26-31; 23:46-51; 24:45-51; 24:66-25:5; 25:24-29; 25:48-54; 26:24-29; 44:60-45:31; 47:58-49:7; 52:4-8; 56:45-57; 57:17-31; 59:32-60:48; 66:13-22; 69:19-62; 77:43-55; 78:58-79:5; 84:62-86:24; 86:56-67; 87:11-22; 88:19-26; 87:1-2); Kowligi '782 (Abstract; Figs. 1-3; col. 1:18-64; 2:15-20; 2:38-3:4; 3:7-12; 3:27-38; col. 4:1-5; col. 4:16-39; 4:64-66; 5:4-7; 5:16-21; 7:49-8:9; 8:38-44; 9:65-10:6; 10:18-67); Lambert '922 (Abstract; 1:46-55; 1:62-65; col. 2:16-35; 2:40-50; 2:55-67; 3:8-12; 3:15-61; 4:10-17; 5:56-6:34; 7:29-32; 7:38-41; 7:55-58; 8:1-6; 8:62-9:19; 9:31-37; 10:54-64; 11:49-56; 11:65-12:13; 12:21-22; 12:27-30; 12:40-64; 13:10-19); Lambert '308 (Abstract; p. 2:10-19; 2:25-30; 3:10-31; 4:2-12; 4:17-31; 5:15-28; 6:15-28; 10:17-11:15; 13:20-24; 15:25-16:14; p.16:27-34; claim 1:1-14; claim 8; claim 10:1-3; claim 11; claim 14; claim 16; claim 19:1-31; claim 20; claim 22; claim 23:1-14; claim 26; claim 27:1-5); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711 (Col. 2:44-3:6; 3:16-21; 3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 50:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21;

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13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-40; 5:19-21; 5:32-34; 3:52-56; 5:65-6:2; 7:28-36; 8:17-22; 8:28-32; 8:67-9:8; 9:15-23; 9:24-32; 9:42-46); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland

'100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages

166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

42. **Bawa '279** renders obvious in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3;

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39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 50:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col.

6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22; 10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36;

5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-40; 5:19-21; 5:32-34; 3:52-56; 5:65-6:2; 7:28-36; 8:17-22; 8:28-32; 8:67-9:8; 9:15-23; 9:24-32; 9:42-46); Zaffaroni '254 (Abstract; Figs. 4, 6; col. 1:19-23; 2:6-9; 2:16-26; 3:5-10; 3:42-45; 3:48-53; 4:15-17; 4:21-28; 4:41; 4:47-58; 5:3-11; 5:65-68; 6:27-30; 7:1-8; 7:18-25; col. 17:67-19:21); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman &

Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

43. **Aebischer '627** renders obvious by itself and/or in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6-5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42;

9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38); Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40; 30:49-53; 31:62-64; 36:21-62; 36:65-37:31; 37:34-48; 37:56-60; 37:63-38:23; 38:24-38; 38:47-60; 39:39-41; 40:33-34; 40:37-42; 49:27-31); Hunter '981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47; 7:12-16; Fig. 13; Fig. 14; Fig. 17E; 11:56-59; 12:23-46; 12:55-59; 12:64-13:37; 13:40-52; 13:54-14:67; 15:3-16:56; 16:66-17:26; 17:41-43; 17:63-18:7; 18:15-49; 22:3-7; 22:21-64; 23:6-13; 23:26-31; 23:46-51; 24:45-51; 24:66-25:5; 25:24-29; 25:48-54; 26:24-29; 44:60-45:31; 47:58-49:7; 52:4-8; 56:45-57; 57:17-31; 59:32-60:48; 66:13-22; 69:19-62; 77:43-55; 78:58-79:5; 84:62-86:24; 86:56-67; 87:11-22; 88:19-26; 87:1-2); Kowligi '782 (Abstract; Figs. 1-3; col. 1:18-64; 2:15-20; 2:38-3:4; 3:7-12; 3:27-38; col. 4:1-5; col. 4:16-39; 4:64-66; 5:4-7; 5:16-

21; 7:49-8:9; 8:38-44; 9:65-10:6; 10:18-67); Lambert '922 (Abstract; 1:46-55; 1:62-65; col. 2:16-35; 2:40-50; 2:55-67; 3:8-12; 3:15-61; 4:10-17; 5:56-6:34; 7:29-32; 7:38-41; 7:55-58; 8:1-6; 8:62-9:19; 9:31-37; 10:54-64; 11:49-56; 11:65-12:13; 12:21-22; 12:27-30; 12:40-64; 13:10-19); Lambert '308 (Abstract; p. 2:10-19; 2:25-30; 3:10-31; 4:2-12; 4:17-31; 5:15-28; 6:15-28; 10:17-11:15; 13:20-24; 15:25-16:14; p.16:27-34; claim 1:1-14; claim 8; claim 10:1-3; claim 11; claim 14; claim 16; claim 19:1-31; claim 20; claim 22; claim 23:1-14; claim 26; claim 27:1-5); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711 (Col. 2:44-3:6; 3:16-21; 3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 50:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59;

12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 3:38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col. 3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-

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101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50); Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

44. **Palmaz '665** renders obvious in combination with one ore more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823

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164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102, 105, 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

45. **Zaffaroni '254** renders obvious in combination with one or more of Peterson '166 (Abstract; col. 1:28-38; 1:51-55; 1:60-62; 1:67-2:5; 2:40-60; 3:67-4:19; 4:56-5:2; 6:28-62; 6:65-7:28; 7:32-53; 7:57-8:28; 8:34-49; 11:23-12:4; 12:14-24; 12:28-30); Schwartz '823 (Abstract; Figs. 6-9, 13, 15; col. 1:9-14; 1:17-19; 1:53-55; 2:8-24; 2:29-54; 2:59-68; 3:48-4:7; 4:13-27; 4:49-5:41; 5:59-6:2; 6:17-38; 6:40-47; 6:49-52; 6:58-68; 7:1-8:11; 8:19-41; 8:46-47); Scott '928 (Abstract; Fig. 3; col. 4:12-14; 4:53-55; 4:58-68; 5:26-6:45; 6:49-59; 6:64-68; 7:55-68; 8:8-60; 9:12-16; 9:67-10:3; 10:24-68; 11:1-7; 11:11-12; 11:22-23; 12:1-22); Tartaglia '113 (Abstract; Fig. 3, 15, 16; 1:7-10; 1:12-20; 1:25-38; 1:42-2:2; 2:23-33; 2:48-55; 3:30-32; 3:36-41; 3:51-60; 4:15-5:10; 5:15-7:7; 7:11-21; 7:23-53; 7:56-65; 8:1-65; 9:3-22; 9:63-67; 10:12-30; 10:40-47; 11:4-24; 12:11-14); Wolff '208 (Abstract; Fig. 5; col. 1:11-13; 1:52-2:9; 2:7-30; 5:6:5-10; col. 23:6:36-38; 6:56-67; 7:19-23; 7:53-55; 7:59-8:31; 8:40-9:33; 9:39-42; 9:56-11:20; 11:47-48; 11:50-53; 12:1-15); Berg '354 (Pages 2:3-4; 2:14-18; 2:27-36; 2:43-58; 3:7-13; 3:16-23; 3:29-34; 3:54-55; 4:5-27; 4:31-40; 5:28-29; 5:53-6:1; 6:6-11; 6:15; 6:17-19; 6:24-35; 6:40-42; 6:46-51; 6:53-55; Table 1); Buscemi '450 (Abstract; Fig. 2; col. 1:58-60; 2:3-6; 2:16-17; 2:24-25; 2:49-52; 2:55-61; 3:9-12; 3:14-15; 3:21-25; 3:53-55; 4:1-5; 4:12-16; 4:19-25; 4:28-44; 4:46-5:5; 5:11-60; 5:64-6:28; 6:31-59; 6:65-7:9; 7:21-24; 7:27-29; 7:32-8:24; 8:27-30); Ding '536 (Abstract; Fig. 1; col. 1:24-32; 1:34-45; 1:48-51; 2:38-46; 3:5-9; 3:19-27; 3:50-4:11; 4:19-5:56; 5:60-6:6; 6:16-48; 7:24-35; 10:35-40; 12:20-23; 12:62-13:2; 13:13-28; 13:37-40; 14:1-38);

Dinh '227 (Abstract; Fig. 1, 2, 9, 10, 14; col. 1:32-35; 2:26-32; 2:35-37; 2:51-54; 2:57-66; 3:1-3; 3:10-22; 3:25-38; 3:41-46; 3:64-65; 4:4-5; 5:3-7; 5:44-57; 6:13-22; 6:26-67; 7:10-23; 7:30-51; 7:56-64; 7:67-8:27; 8:26-43; 8:49-60; 8:64-9:3; 9:17-24; 9:49-50; 9:53-10:31; 11:25-30; 11:60-62; 12:24-28; 12:38-50; 12:54-60); Domb '055 (Abstract; col. 1:12-18; 3:54-57; 4:15-17; 4:22-36; 5:24-6:18; 6:24-26; 6:33-40; 6:42-7:3; 7:10-20; 7:25-29; 7:40-52; 9:15-30; 9:55-10:2; 10:21-52; 10:60-11:11; 11:27-44; 12:1-7; 12:11-42); Fox '096 (Abstract; col. 1:33-36; 1:64-2:5; 2:9-21; 2:48-65; 3:55-67; 4:30-5:35; 7:22-25; 7:28-32; 11:34-48; 11:51-56; Table IV; 12:24-41; 13:36-51; 14:47-53; 15:20-33; 16:16-23; 18:19-25; 19:11-16; 20:54-58; 22:31-37; 28:13-18; 29:38-40; 30:49-53; 31:62-64; 36:21-62; 36:65-37:31; 37:34-48; 37:56-60; 37:63-38:23; 38:24-38; 38:47-60; 39:39-41; 40:33-34; 40:37-42; 49:27-31); Hunter '981 (Col. 1:12-17; 3:39-4:3; 4:14-5:47; 7:12-16; Fig. 13; Fig. 14; Fig. 17E; 11:56-59; 12:23-46; 12:55-59; 12:64-13:37; 13:40-52; 13:54-14:67; 15:3-16:56; 16:66-17:26; 17:41-43; 17:63-18:7; 18:15-49; 22:3-7; 22:21-64; 23:6-13; 23:26-31; 23:46-51; 24:45-51; 24:66-25:5; 25:24-29; 25:48-54; 26:24-29; 44:60-45:31; 47:58-49:7; 52:4-8; 56:45-57; 57:17-31; 59:32-60:48; 66:13-22; 69:19-62; 77:43-55; 78:58-79:5; 84:62-86:24; 86:56-67; 87:11-22; 88:19-26; 87:1-2); Kowligi '782 (Abstract; Figs. 1-3; col. 1:18-64; 2:15-20; 2:38-3:4; 3:7-12; 3:27-38; col. 4:1-5; col. 4:16-39; 4:64-66; 5:4-7; 5:16-21; 7:49-8:9; 8:38-44; 9:65-10:6; 10:18-67); Lambert '922 (Abstract; 1:46-55; 1:62-65; col. 2:16-35; 2:40-50; 2:55-67; 3:8-12; 3:15-61; 4:10-17; 5:56-6:34; 7:29-32; 7:38-41; 7:55-58; 8:1-6; 8:62-9:19; 9:31-37; 10:54-64; 11:49-56; 11:65-12:13; 12:21-22; 12:27-30; 12:40-64; 13:10-19); Lambert '308 (Abstract; p. 2:10-19; 2:25-30; 3:10-31; 4:2-12; 4:17-31; 5:15-28; 6:15-28; 10:17-11:15; 13:20-24; 15:25-16:14; p.16:27-34; claim 1:1-14; claim 8; claim 10:1-3; claim 11; claim 14; claim 16; claim 19:1-31; claim 20; claim 22; claim 23:1-14; claim 26; claim 27:1-5); WO 94/21309 (Abstract; p.1:4-8; 1:56-2:10; 2:29-30; 3:11-13); Mitchell '711 (Col. 2:44-3:6; 3:16-21;

3:24-31; 5:3-17; 6:24-28; 7:16-20; 7:56-8:7; 8:22-23; 8:39-42; 8:49-56); Morris '781 (col. 2:20-39; 3:45-56; 3:67-4:4; 4:10-21; 9:66-10:33; 10:50-54; 11:41-45; 12:29-35; 12:36-42); Morris '182 (page 2:44-54; 3:24-30; 3:45-52; 6:27-31; 6:54-56; 7:27-29; 7:57-8:1; 8:8-9; col. 8:15-16); Myler '563 (Abstract; Figs. 1, 2, 13; col. 1:11-12; 2:10-16; 2:20-28; 2:53-58; 3:13-15; 3:33-37; 3:44-46; 3:48-54; 3:58-61; 4:9-12; 4:30-43; 4:53-67; 5:1-16; 5:24-26; 5:39-46; 50:50-54; 6:18-23; 10:12-14; 10:56-61; 11:55-58; 11:63-65; 12:11-13; 12:19-23; 12:28-33; 12:54-13:1; 13:5-17; 13:61-66; 18:51-19:9; 19:18-32; 19:61-63; 19:65-20:7; 20:33-49; 20:51-57; 22:10-13); Palmaz '417 (Abstract; Figs. 1A, 1B, 3, 5, 6, 8, 9, 10; col. 1:17-23; 3:56-4:7; 4:25-37; 5:1-20; 5:26-43; 5:66-68; 6:6-9; 6:20-54; 6:63-7:2; 7:64-8:2; 8:36-60; 10:6-14; 11:3-34; 12:33-38; 12:19-21; 12:33-38; 12:41-66; 13:20-40; 13:51-53; 14:17-19; 14:27-29; 14:39-59; 15:18-40; 15:33-40; 15:53-16:5; 16:18-37; 16:45-54; 16:59-67); Tice '330 (Col. 3:20-33; 4:65-6:27; 8:38-68); Thies '317 (Abstract; col.1:15- 2:26-38; 2:43-51; 3:41-4:2; 6:35-39; 7:36-11:68; 12:10-40; 13:4-14:3); Tice '840 (Col. 2:18-34; 2:38-3:8; 10:56-11:15; 12:6-9); Tice '025 (Col. 2:18-34; 2:38-3:8; col. 10:51-11:5; col. 12:1-4); Lapka '244 (Abstract; col. 2:35-63; 4:35-5:5; 32:5-16; 32:20-21; 32:28-39); Kent '189 (Abstract; col. 1:12-28; 1:50-65; 2:4-7; 2:19-32; 2:48-10:12; 11:5-13:35; 17:42-18:67); Tice '268 (Abstract; col. 1:32-46; 1:47-2:14; 2:45-53; 3:40-47; 11:15-41; 11:47-59; 12:55-68); Aebischer '486 (Abstract; Figs. 1 and 2; col. 2:60-63; 3:7-23; 3:34-38; 3:56-63; 4:29-34; 4:38-5:11; 5:18-6:10; 6:17-22; 6:27-8:30; 9:18-10:12); Folkman '560 (Col. 1:56-2:23; 2:43-68; 3:18-23; 3:36-51; 3:52-4:68; 5:1-9; 6:61-7:50; 8:17-18; 10:11-14; 11:41-47; 11:56-12:43; 12:52-54; 12:59-61); Cohen '496 (Col. 2:30-36; 2:46-66; 3:26-63; 3:65-5:16; 6:59-64; 7:57-8:12; 9:40-10:43); Schiraldi '243 (Abstract; col. 1:8-21; 1:58-60; 2:21-25; 2:30-63; 3:3-53; 4:7-12; 4:67-5:27; 9:36-55; 10:3-7; 10:12-30); Helwing '868 (Abstract; col. 1:6-16; col. 1:19-37; col. 1:38-2:11; col. 2:12-24; col. 2:25-37; col. 38-53; col. 2:55-3:27; col. 3:37-43; col. 3:47-50; col.

3:62-66; col.3:67-4:17; col. 4:18-38; col. 4:39-5:6; col. 5:7-46; col. 5:47-50; col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20; col. 7:21-8:50; col. 8:51-9:29; col. 9:30-52; col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48; col. 12:49-13:5; col. 19:57; col. 20:18-37; col. 20:46-54; col. 20:55-68; col. 21:27-41; col. 21:42-46; col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3; col. 23:4-col. 24:27); Valentini '029 (Abstract; Fig. 3; col. 1:56-2:4; col. 2:29-3:25; 3:62-67; 4:46-59; 5:13-6:12; 6:14-42); Greco '135 (Abstract; col. 1:19-26; 1:29-2:59; 3:8-19; 3:22-27; 3:30-43; 3:48-4:39; 4:43-5:26; 5:30-6:58; 7:46-9:3; 9:10-26); Bawa '279 (Abstract; col. 1:16-36; 2:8-15; 2:27-35; 2:39-45; 2:47-68; 4:14-25; 6:40-44; 6:50-57; 7:15-21; 8:1-6; 8:29-49; 8:50-55; 8:66-68; 9:42-10:24; 11:42-12:9; 12:29-34; 13:10-17; 13:26-14:14); Aebischer '627 (Abstract; col. 3:32-4:3; 4:11-27; 5:52-6:33; 6:52-8:14; 7:3-28; 7:57-8:14; 10:31-34; 13:31-48; 13:66-68; 14:1-2; 14:22-32; 14:45-49; 14:54-58); Wood '066 (Abstract; 2:55-3:32; 3:47-7:4; 7:6-32; 7:43-65; 8:55-56; 17:19-22; 17:30-34; 18:1-4; 18:13-16; 18:26-30; 23:4-26:18); Strecker '746 (Abstract; Figs. 4, 7, 8; col. 1:12-22; 1:56-2:2; 2:12-15; 2:21-38; 2:47-53; 2:59-3:33; 3:41-4:31; 5:10-12; 5:18-20; 5:34-64; 6:1-17; 6:30-44; 6:50-55; 6:59-62; 7:1-10; 7:16-44; 7:48-65; 8:4-9; 8:10-10:19); Lambert '246 (Abstract; col. 1:57-61; 2:15-34; 2:38-49; 2:53-3:48; 3:50-4:35; 7:31-33; 8:58-9:4; 9:31-37; 10:45-12:54); Bellamkonda '029 (Abstract; Fig. 6; col. 2:65-3:5; 4:9-14; 4:18-39; 4:48-57; 5:10-14; 5:32-48; 7:13-32; 9:36-48; 10:28-11:13; 11:33-50; 12:13-25; 12:42-56; 15:67-16:17; 19:7-16; 19:33-22:37; 23:54-24:55); Dayton '382 (Abstract; Figs. 4, 7, 9, 10, 12, 14; col. 1:9-17; 3:36-39; 3:62-4:17; 4:24-50; 4:54-5:3; 5:50-60; 6:64-7:14; 7:20-23; 7:26-29; 7:34-66; 8:4-33; 8:42-59; 8:64-9:5; 10:1-10); Burt '036 (Fig. 14B; p. 4:9-33; 10:17-25; 11:11-23; 14:9-27; 21:2-4; 21:14-22:6; 45:32-46:27; 51:1-52:35); Goldin '568 (Abstract; Fig. 1A, 1B, 5A-5F; col. 1:21-41; 1:43-62; 2:1-6; 2:8-16; 2:24-29; 3:42-65; 4:25-57; 4:63-66; 5:28-34; 6:1-29; 8:65-9:12; 9:18-30; 9:43-55; 10:12-22;

10:45-58; 11:6-9; 11:58-12:14; 13:53-65; 14:1-28; 14:66-15:67; 17:40-54; 18:23-23:3; 23:6-26:5; 25:59-26:5; 27:10-18; 31:57-32:7; 32:16-22; 32: 26-31); Palmaz '665 (Abstract; Figs. 1A, 1B, 2A, 2B, 4, 5, 6; col. 1:11-17; 2:64-3:7; 3:20-25; 3:33-39; 3:47-51; 3:55-65; 4:1-6; 4:33-36; 5:9-13; 5:25-32; 5:55-65; 4:24-48; 6:4-11; 7:20-25; 8:9-14; 8:59-64; 9:7-15); Palmaz '762 (Abstract; Figs. 4 & 5; col. 1:19-25; 3:34-37; 3:45-51; 3:65-4:2; 4:6-19; 4:43-46; 4:53-56; 5:43-45; 6:9-13; 6:18-24; 8:7-21; 9:1-6; 9:20-25; 9:68-10:10; 10:17-25; 10:28-48); Palmaz '337 (Abstract; Figs. 4, 5, 6; col. 1:24-30; 3:1-12; 3:27-30; 3:37-44; 3:52-56; 3:60-4:2; 4:29-34; 4:36-40; 5:19-21; 5:32-34; 3:52-56; 5:65-6:2; 7:28-36; 8:17-22; 8:28-32; 8:67-9:8; 9:15-23; 9:24-32; 9:42-46); Laurencin '630; Montano '877; Pitt '656; Rowland '100; Wokalek '265; Leong '843; Collombel '187; Rhee '775; Herweck '681; Sintov '953; Cini '093; Keefer '447; Hunter '341; Rowe '358; Szycher '590; Coury '308; Wiktor '062; Aishima '449; Aebischer '844; Keefer '919; Saffran '262; Keefer '357; Palmaz '341; Chadwick '821; Urry '592; Wolff '779; Kopia '120; Kinsella '608 (Col. 5:43-57; 6:8-12; 11:14-24); Mano '711; Folkman '797; Larm '665; Scharnberg '720; Pinchuk '048; Tormala '051; Slepian '580; Silvestrini '456; Jernberg '271; Sahatjian '121; Berg '650; Slepian '815; Sahatjian '192; Fearnot '629; Tuch '411; Wolff '567; Langer I (pages 27-30); Langer II (pages 217-25); Langer III (pages 25-28; Figs. 3-3, 3-4); Langer & Peppas (pages 80-101, 114-16; Figs. 5, 7); Langer IV (pages 36-37, 41-42, 44; Figs. 2, 3, 4); Langer V (page 24); Langer VI (pages 115, 120-24); Laurencin & Langer (pages 304-309, 313-16; Figs. 2, 4, 5); Langer VII (pages 1529-32; Figs. 1(B), (C), and (D)); Langer & Moses (pages 341-44); Chien (pages 32-33, 37); Thomson (pages 34-36); Hanes & Langer (pages 647-649, 652, 654-58; Fig. 29.2); Batz (pages 26-27, 36-43, 48); Donaruma (pages 10, 17, 19-20); Harris I (pages 334, 344); Feld (pages 113-19); Harris & Post I (page 622); Harris & Post II (page 225); Drobnik (pages 2833-34, 1844-47); Allan I (pages 17-19); Allan II (pages 349-50);

Allan III (pages 173-74, 176); Jakubke (pages 281-83; Fig. 2); Engelberg & Kohn (pages 292-302; Table 1); Roseman & Mansdorf (pages 91-105, 107-117; Figs. 2 & 3); Lee & Good (pages 2-7, 17, 182, 188-200, 214-30); Langer & Folkman I (pages 179-192); Langer & Folkman II (pages 798-99); Langer VIII (pages 1, 10, 27-34; Figs. 20, 22); Langer & Folkman III (pages 114-15, 117-20, 123-26); Rhine (pages 265, 267-69); Aebischer (pages 282-83, 286; Table 1); Langer IX (pages 267, 269, 276; Table 1); Langer X (pages 179-87, 192, 195-200); Langer XI (pages 95-96); Brown (pages 1181, 1184); Kost & Langer (pages 47-49); Hsu & Langer (pages 445-46, 459); Bawa (pages 259, 263, 266); Leong & Langer (pages 202-03, 206-215, 219-23); Baker (pages 14-16, 161-65); Langer XII (pages 162-164); Langer XIII (pages 166, 170); Chasin (pages 43-45, 47-62); Langer XIV (pages 538-42); Brem (pages 2-6); Langer XV (pages 102. 105. 109); Thompson (pages 31-44); Chandrasekaran (pages 587-88); Kim (pages 194-206, 215-23, 226-46; Fig. 4); Langer & Peppas II; Aebischer II; Peterson; Dev (Abstract; p.273-75, 277); Lambert; Aebischer III (page 474); Aebischer IV (pages 599-600).

The asserted claims of the Saffran '760 patent are invalid based upon the predictable use of well-known elements from the exemplary prior art identified above, according to their established functions. Generally, the reason to combine these references can be found – explicitly or implicitly – in the nature of the problem to be solved, the knowledge of the skill in the art in the 1995 time frame, the relation of the references to the subject matter at issue, the body of the references themselves, and/or the prior art as a whole.

In describing the claimed invention, Saffran's specification focuses largely on treatment of broken bones. In the Background of the Invention, the specification explains that broken bones often do not heal properly: "Complex fractures often heal with poor results." Col. 2:11. The specification identifies "interrupt[i]ons" in the healing process as a cause of this

problem. Col. 2:12-16. It explains that the body initiates a natural healing process after a bone fracture. Macromolecules that aid in healing are "secreted into the interfragmentary space [*i.e.*, the space between the fragments of a broken bone]." Proper healing occurs "[i]f the concentration of these macromolecules remains high enough" Col. 2:17-22.

Unfortunately, the optimal "concentration of these macromolecules within the interfragmentary space," id., is not always achieved because the beneficial macromolecules "[o]ften ... diffuse into surrounding tissue." Col.2:41-43. This "efflux of growth-promoting proteins" disrupts the healing process and "is harmful" Col. 2:42-45. It leaves "insufficient growth-promoting macromolecules within the interfragmentary space," causing broken bones not to heal properly. Col. 2:59-60.

Some researchers had proposed using a "porous substrate" to treat bone fractures. "The critical feature of these devices is that they contain pores large enough to permit cells to grow into them." Col. 3:50-67. Saffran was critical of this approach because macromolecules – which are "orders of magnitude smaller than cells" – are "not restrained within the interfragmentary space" and instead are "free to exit the interfragmentary space and pass unhindered into the surrounding tissue." Id.

While it is desirable to restrain macromolecules within the interfragmentary space, it also is desirable to allow free passage of small molecules or metabolites: "[I]f small molecules such as water, urea, bicarbonate, and hydrogen ions are permitted to pass through the device, healing occurs much more quickly." Col. 5:19-22. Thus, devices that are completely "non-porous" to small molecules are undesirable because they "hinder the passage of desirable small molecules such as glucose and water into the interfragmentary space." Col. 5:28-31.

The specification summarizes what Saffran viewed as lacking in the art: "Clearly, what is needed is a device that can restrain macromolecules but allow free passage of small molecules." Col. 5:31-33.

The specification also teaches that the device should be a thin, single layer sheet to minimize the material implanted into the patient and increase ease of percutaneous delivery. Col. 6:16-18, 20-23. The device should further possess a mechanism for release of "treating material . . . in a more controlled manner than by mechanical efflux through pores." Col. 6:18-20. The solution, according to Saffran, lies in the "ability of medications to stick to the single sheet of minimally-porous material." The "thinness" of a single, rather than a dual layer device is important because it provides the ability to "more easily apply the healing benefits" of the device to "blood vessels." Col. 21:63-67. Furthermore, the specification claims that attachment of medicines to the surface of the layer results in a significant "improvement in [] medicine release kinetics" and "unprecedented specificity of [drug] release" compared to the "random diffusion of medicine from micropores" found in systems in which the drug is held within the polymer and released by diffusion. Col. 14:53-58, 22:14.

Accordingly, the specification describes the invention as a "single-layered, malleable fixation device." Such a device is capable of "containing macromolecules produced by the injured tissue at the site of injury" but "permits the free passage of small metabolites and water through pores in the device." In addition, the treating material is affixed to the device "using chemical bonds such that medicines are released [in a controlled manner] according to the rate constant rather than random diffusion." Finally, the treating material is released in a directional matter "directly and specifically" to the site of injury. Col. 6:26-40; 7:7-10.

The problems and solutions identified in the '760 specification were recognized throughout the art by 1995. In particular, the use of flexible polymer layers for local delivery of drugs was well known in the art. See, e.g., Scott '928 at, e.g., col. 16:59-62 ("The flexible film can be applied as a sheath to the metal stent elements after which the stent can be compressed, attached to a catheter, and delivered through the body lumen to a desired location."), col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents luminally to anticoagulate the blood flow surface."); Schwartz '823 at, e.g., col. 2:29-37 ("In a radially expandable stent for implantation within a body lumen, the stent having a generally cylindrical body with open proximal and distal ends, the cylindrical body comprising a plurality of metal elements joined to permit flexing of the cylindrical body along its longitudinal axis to permit the stent to conform to a curved body lumen, the improvement of the present invention comprises a polymeric film extending between the metal elements."), col. 8:5-11 ("The resulting stent has microcapsules containing one therapeutic substance on the inside (and able to contact blood once implanted in a blood vessel) and the microcapsules containing a second therapeutic substance on the outside (and able to contact the vessel wall when implanted in contact with the vessel wall.)"); Tartaglia '113 at, e.g., Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member."), col. 1:15-19 ("Ideally, implantation of such stents is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."), col. 5:49-66 ("The polymeric material is preferably selected from thermoplastic and elastomeric polymers. . . . In another currently preferred

embodiment, the polymeric material can be ethylene vinyl acetate (EVA) The polymeric material is preferably bioabsorbable, and is preferably loaded or coated with a therapeutic agent or drug. . ."), 7:11-18 ("The polymeric film material also currently preferably includes a plurality of apertures so that the polymeric material is porous, to allow blood flow through the stent structural member to the vessel wall, such as for oxygenation and nutrient exchange to the vessel wall . . ."); Kowligi at, e.g., col. 1:28-32 ("The use of implantable prosthetic vascular grafts made of expanded, porous PTFE is well known in the art. Such vascular grafts are often implanted just below the skin to provide blood access for long term hemodialysis."), col.1:42-43 ("Expanded porous PTFE material offers a number of advantages when used as a prosthetic vascular graft."); Peterson '166 at, e.g., col. 1:51-55 ("Another object of the instant invention is to provide a bioactive compound via covalent bonding to a polymeric backbone so that upon hydrolysis of said covalent bond said bioactive compound is released in active, unmodified form."), col. 1:60-2:5 ("The system comprises a polymeric biodegradable carrier and a bioactive compound attached to the carrier by a hydrolysable bond The bioactive compound may be any compound which can be attached covalently, that is, by a hydrolysable bond, to the carrier polymer, either directly or indirectly through a chemical space unit. The delivery system is usually implanted subcutaneously by injection or incision in an animal, including the human body."). One of ordinary skill in the art would have been motivated to combine prior art references by the nature of this problem.

As was known to those skilled in the art at the time of the alleged priority dates of the Saffran '760 patent, and as taught by the references disclosed herein, the asserted claims of the Saffran '760 patent represent combinations of familiar elements of the prior art, according to known methods that yield predictable results. For example:

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(1) A layer of flexible material minimally porous to macromolecules: The prior art is replete with examples of stents with polymer coated struts and stents covered by polymer sheaths which are implanted within blood vessels for the treatment of cardiovascular diseases. See, e.g., Scott '928 at, e.g., col. 16:59-62 ("The flexible film can be applied as a sheath to the metal stent elements after which the stent can be compressed, attached to a catheter, and delivered through the body lumen to a desired location."); Schwartz '823 at, e.g., col. 2:29-37 ("In a radially expandable stent for implantation within a body lumen, the stent having a generally cylindrical body with open proximal and distal ends, the cylindrical body comprising a plurality of metal elements joined to permit flexing of the cylindrical body along its longitudinal axis to permit the stent to conform to a curved body lumen, the improvement of the present invention comprises a polymeric film extending between the metal elements."); Myler '563 at, e.g., col. 3:44-48 ("The stent can be balloon expandable, self expanding, thermally expandable or expandable by other means and still incorporate the inventions described herein. Metal mesh or woven walled stents are well suited for expansion on a dilation catheter, as discussed infra."); Palmaz '417 at, e.g., Abstract ("A plurality of expandable and deformable intraluminal vascular grafts are expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."), col. 11:11-14 ("The coating [over the struts of the open-mesh stent] should be thin and highly elastic so as not to interfere with the desired expansion and deformation of prosthesis, or graft."); Berg '650 at, e.g., col. 3:29-35 ("The underlying structure of the stent can be virtually any stent design, whether of the self-expanding type or of the balloon-expandable type and whether metal or polymeric. Thus metal stent designs such as those disclosed in U.S. Pat. No. 4,733,665 issued to Palmaz, U.S. Pat. No.

4,800,882 issued to Gianturco or U.S. Pat. No. 4,886,062 issued to Wiktor could be used in the present invention.").

Furthermore, by 1995, flexible layers "minimally porous to macromolecules" were well-known to persons of ordinary skill in the art. See, e.g., Aebischer '627 at, e.g., col. 4:11-27 ("The term 'semipermeable' is used herein to describe biocompatible membranes that allow the diffusion therethrough of molecules having a relatively low molecular weight, while excluding the passage of those having a relatively high molecular weight. . . . The semipermeable membrane can be made of various polymeric compositions such as polyvinylchloride, polyacrylonitrile, polyvinylidene fluoride, polystyrene, polymethylmethacrylate, polysulfone, and acrylic copolymers."); Valentini '029 at, e.g., col. 2:32-54 ("Medical devices employing such selectively permeable materials . . . are disclosed for use in regenerating nerves. The devices can be formed from various polymeric materials The terms 'semipermeable' and 'selectively permeable' are used herein to describe materials which are capable of allowing the exchange of nutrients and other metabolites with the regenerating nervous tissue while excluding fibroblasts and other scar-forming cells. Preferably, the materials allow passage therethrough of solutes having a molecular weight of about 100,000 daltons or less. The nerve guidance channels of the present invention are also preferably designed to retain nerve growth factors secreted at the anastomatic site or seeded therein, as well as retain any luminal matrix material placed inside the guidance channels."); Folkman '560 at, e.g., col. 3:18-23 ("The polymer matrixes, which are suitable used in the present invention . . . are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith.").

Indeed, according to the specification, most polymers are suitable as "minimally porous" layers. Col. 15:24-28 ("[The device] can be manufactured with any other material that meets the criteria of minimal-porosity and macromolecular containment including . . . a synthetic polymer, a biological polymer, or a biodegradable biological polymer . . ."). The use of both biostable and biodegradable polymer coatings on stents dates back well before the 1990s. See, e.g., Palmaz '417 at, e.g., col. 11:29-34 ("Such absorbable polymers include polyglycoides, polylacoides, and copolymers thereof. Such absorbable polymers could also contain various types of drugs, whereby . . . the drug would be slowly released into the body passageway."); Tartaglia '113 at, e.g., col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); Domb '055 at, e.g., Abstract ("Devices are provided having a polymer coating incorporating compounds inhibiting inflammation and infection, along with subsequent tissue growth onto and around the device. . . . Preferred polymeric coatings are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); Scott '928 at, e.g., col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); Ding '536 at, e.g., col. 1:24-27 ("The present invention relates generally to providing biostable elastomeric coatings on the surfaces of implants which incorporate biologically active species having controlled release characteristics in the coating . .

"); Folkman '560 at, e.g., col. 3:52-54 ("In the presently preferred embodiment the polymeric materials useful for forming the matrix [include] ethylenevinyl ester copolymers . . .").

(2) Directional release of treatment compound: The value of directional drug release has long been recognized and taught in the prior art as a means for ensuring local delivery of drugs. Moreover, by 1995, directional drug release by polymer coatings on drug-eluting stents and polymer sheaths for such stents was widely known by persons of ordinary skill in the art. See, e.g., Scott '928 at, e.g., col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents luminally to anticoagulate the blood flow surface."); Schwartz '823 at, e.g., col. 8:5-11 ("The resulting stent has microcapsules containing one therapeutic substance on the inside (and able to contact blood once implanted in a blood vessel) and microcapsules containing a second therapeutic substance on the outside (and able to contact the vessel wall when implanted in contact with the vessel wall)."); Wolff '208 at, e.g., col. 6:5-8 ("When the drugs are delivered locally via the [stent], they may be at the therapeutic levels at the diseased site while at the lower limits of detectability in the bloodstream.").

Plaintiff specifically assert that directional release results from placement of the treating layer "adjacent to the damaged tissue" in combination with the hydrophobic nature of sirolimus, which together causes a "diffusion gradient" which "favors elution [of the drug] into tissue." Infringement Contention, at 12-13. The prior art, however, discloses the release of hydrophobic drugs from hydrophobic polymers. See, e.g., Hunter '981 at, e.g., col. 18:15-17 ("Within further aspects of the present invention, polymeric carriers are provided which are adapted to contain and release a hydrophobic compound . . ."), col. 86:63-64 ("4. a stent

according to claim 1 wherein said [hydrophobic] polymeric carrier comprises a poly (lactic acid)."); Morris '781 at, e.g., col. 11:41-43 ("Rapamycin . . . can be administered intravascularly or via a vascular stent impregnated with rapamycin . . ."), col. 10:50-54 ("Suitable solid carriers include . . . talc . . . [and] low melting waxes . . ."); Lambert '922 at, e.g., col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion."), col. 3:29-31 ("Biologically active compounds presently preferred for use in the practice of the present invention include lipophilic compounds . . ."); Schwartz '823 at, e.g., col. 3:66-4:3 ("[T]he stent may also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 "Intraluminal Drug Eluting Prosthesis", which is incorporated by reference herein."), col. 4:14-20 ("The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, or composites thereof."); Wood '066 at, e.g., col. 4:45-7:4 (disclosing hydrophobic treating materials), col. 7:6-32 ("The release of therapeutic agents from the bandage has been found to be further controllable by including insoluble particles capable of adsorbing or forming salts with the therapeutic agent in the bandage. . . . Other examples of suitable insoluble particles include hydrophobic resins, silica, hydroxyl apatite and aluminum oxide."). In addition, the prior art discloses the use of hydrophobic polymer carriers for the release of a wide variety of drugs as well as the release of rapamycin by a variety of different polymeric carriers. See, e.g., Ding '536 at, e.g., col. 5:54-65 ("The above-referenced [polymer] materials are considered hydrophobic with respect to the contemplated environment of the invention. . . . [A]gents possibly suitable for incorporating [into the polymers] include . . . agents that inhibit hyperplasia and in particular restenosis . . .");

Domb '055 at, e.g., col. 4:33-36 ("Preferred polymeric coatings are . . . formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); Mitchell '711 at, e.g., col. 4:5-6 ("A vascular stent can be impregnated with either rapamycin or heparin . . ."). It would be obvious to one skilled in the art to incorporate hydrophobic treating compounds into hydrophobic polymers to achieve directional drug release.

(3) Material release means for a treating compound: The release of drugs from one or several flexible polymer layers has been known for decades. See, e.g., Langer I at, e.g., p. 28-29; Langer II at, e.g., p. 218-20; Wolff '208 at, e.g., col. 9:23-24 ("[T]he filaments [forming the stent] maybe made from one or several layers of polymer."); Schiraldi '243 at, e.g., col. 1:8-13 ("The present invention relates to a controlled release medicament-containing preparation . . . in the form of a very thin extruded thermoplastic film (which can be in single layer or laminated multi-layer form) . . ."); Myler '563 at, e.g., col. 12:56-61 ("The embodiment illustrated in Fig. 13 shows . . . a single exterior coating. Alternatively, . . . multiple coats of the same or different material could be used on the interior or exterior surface of [a] stent."); Schwartz '823 at, e.g., col. 7:1-8:11 (disclosing two layers of polyurethane containing different therapeutic substances).

The Saffran specification discloses the release of treating material through the hydrolysis or enzymatic degradation of chemical bonds, which it describes as a "highly significant improvement over the prior art." Col. 22:8. Saffran further claims that the methods of drug release disclosed in the prior art "**all** rely on the efflux of treating materials from micropores to deliver medicine."). Col. 22:9-10 (emphasis added). In point of fact, the controlled release of covalently-bound drugs by hydrolysis or the enzymatic degradation of the chemical bond was well-documented in the scientific literature well before the 1990s. Publications by Dr. Robert Langer, a leader in the field of controlled drug release from polymers,

and others frequently described regulation of drug release kinetics through the hydrolysis or enzymatic degradation of the tethering covalent bond. These publications date back to the early 1980s. See, e.g., Langer I at, e.g., p. 29-30 ("The second type of chemically controlled system is known as a pendant chain system. In simplest form, the drug is attached via chemical bonds to a polymer backbone. It could also be attached via a spacer group Release occurs when water reacts to break those bonds, thereby freeing the drug. Release rates are adjusted by varying the hydrophilicity of the polymer backbone. Systems could also be designed so that an enzymatic reaction could break the drug-polymer bonds."); Langer II at, e.g., p.219 Fig. 4 ("Chemically controlled pendent-chain drug-delivery system. Here, the drug is bound to a polymer backbone and released by hydrolytic or enzymatic cleavage."); Langer & Peppas at, e.g., p.86-87 ("Chemically controlled drug release generally involves one of two types of systems . . . 2) pendant chain systems in which the drug is attached to a polymer through a hydrolytically or enzymatically labile linkage. Drug release is influenced by the rate of degradation of this linkage."); Laurencin & Langer at, e.g., p.308-309 ("In [pendant chain systems], drug is chemically bound to the backbone of a polymer. Release takes place by hydrolytic or enzymatic cleavage. . . . Polymer systems can be soluble or insoluble, and the backbone itself may be bioerodible or nonbioerodible."); Chien at, e.g., p.32-33 ("[The hydrolysis-activated] controlled drug delivery system depends on the hydrolysis process to activate the release of drug molecules. . . . [The enzyme-activated] controlled drug delivery system depends on the enzymatic process to activate the release of drug. . . . The release of drugs is activated by the enzymatic hydrolysis of the biopolymers by a specific enzyme in the target tissue.").

The use of such controlled release method was similarly disclosed in the patents granted to Peterson and others. See, e.g., Peterson '166 at, e.g., col. 1:51-55 ("Another object of

the instant invention is to provide a bioactive compound via covalent bonding to a polymeric backbone so that upon hydrolysis of said covalent bond said bioactive compound is released in active, unmodified form."), col. 1:60-2:5 ("The system comprises a polymeric biodegradable carrier and a bioactive compound attached to the carrier by a hydrolysable bond The bioactive compound may be any compound which can be attached covalently, that is, by a hydrolysable bond, to the carrier polymer, either directly or indirectly through a chemical space unit. The delivery system is usually implanted subcutaneously by injection or incision in an animal, including the human body."); Helwing '868 at, e.g., col. 1:13-16 ("The primary uses of the invention are in hydrolysable controlled release utilizations of the active agents in such areas as pharmaceuticals, insecticides, herbicides, and the like."); Lambert '246 at, e.g., col. 1:46-53 ("Release of heparin from intravascular catheters in quantities sufficient to decrease thrombosis on the catheter has been achieved by either covalently bonding a charged molecule to a polymer or incorporating a large nonmobile charged molecule on the surface of a polymer."); Lambert '922 (same); Tartaglia '113 at, e.g., col. 1:60-64 ("The polymeric material [on the outside of the stent] is preferably bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); Schwartz '823 at, e.g., col. 7:14-17 ("Application of the therapeutic substance to the film can include applying it on the surface of the film or incorporating it into the film as it is made."); Berg '354 at, e.g., p. 2:27-29 ("Other methods of providing therapeutic substances to the vascular wall include simple heparin-coated metallic stents, whereby a heparin coating is ionically or covalently bonded to the stent.").

Plaintiff explains that the chemical bonds and linkages described in the '760 patent also occur where hydrophobic treating material is placed within a hydrophobic polymer. See

Infringement Contention, at 13 ("These hydrophobic materials [sirolimus, PEVA, and PBMA] interact to form hydrophobic bonds, which are a type of chemical bonds and linkages . . ."). The prior art, however, discloses the use of hydrophobic drugs in combination with hydrophobic polymers. See, e.g., Hunter '981 at, e.g., col. 18:15-17 ("Within further aspects of the present invention, polymeric carriers are provided which are adapted to contain and release a hydrophobic compound . . ."), col. 86:63-64 ("4. a stent according to claim 1 wherein said [hydrophobic] polymeric carrier comprises a poly (lactic acid)."); Morris '781 at, e.g., col. 11:41-43 ("Rapamycin . . . can be administered intravascularly or via a vascular stent impregnated with rapamycin . . ."), col. 10:50-54 ("Suitable solid carriers include . . . talc . . . [and] low melting waxes . . ."); Lambert '922 at, e.g., col.2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion."), col. 3:29-31 ("Biologically active compounds presently preferred for use in the practice of the present invention include lipophilic compounds . . ."). As discussed supra, the prior art also discloses the use of hydrophobic polymer carriers in combination with a wide variety of drugs as well as the release of rapamycin from a variety of different polymeric carriers. See, e.g., Ding '536 at, e.g., col. 5:54-65; Domb '055 at, e.g., col. 4:33-36; Mitchell '711 at, e.g., col. 4:5-6. It would be obvious to one skilled in the art to incorporate hydrophobic treating compounds into hydrophobic polymers to achieve the claimed controlled drug release.

(4) Formation of a chamber through apposition of the device adjacent to the damaged tissue:

The formation of a chamber by the placement of a polymer layer adjacent to damaged tissue, and the release of drugs into the chamber by the polymer, was disclosed in the prior art as least as early as the mid-1980s. See, e.g., Schiraldi '243 at, e.g., 2:60-63 ("The

[polymeric] film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion), or may allow diffusion of the drug into the oral cavity."); Schwartz '823 at, e.g., col. 2:49-53 ("The polymeric film . . . is capable of conforming to the movements of the metallic stent elements when expanded into contact with a body lumen."); Ding '536 at, e.g., Abstract ("A coating and method for implantable open lattice metallic stent prostheses are disclosed."); Palmaz '417 at, e.g., col. 5:4-20 ("The present invention includes: a plurality of expandable and deformable, thin-walled tubular prostheses . . . whereby upon inflation of the expandable, inflatable portion of the catheter, the prostheses are expanded and deformed radially outwardly into contact with the body passageway."); Wolff '208 at, e.g., col. 6:56-58 ("The stent shown in Figs. 2 and 4 is a metallic malleable design which may be forced against a lumen wall by a balloon catheter which fixes it into position."); Berg '354 at, e.g., p.3:16-18 ("In operation, the stent made according to the present invention can deliver drugs to a body lumen by introducing the stent transluminally into a selected portion of the body lumen and radially expanding the stent into contact with the body lumen.").

EXHIBIT C**Section 102 (Anticipation) and Section 103 (Obviousness)**

Following are the claim charts as required by Local Patent Rule 3.3(c). The citations to the Specification and Figures in the prior art references are illustrative only and there are many other citations to the Specification and Figures that are not illustrated. For each disclosed reference, Defendants intend to rely on the reference in its entirety, rather than only on the identified excerpts thereof.

Claim 1 [1A]: A flexible fixation device for implantation into human or animal tissue to promote healing of a damaged tissue comprising:¹

Where Found in the Prior References

Peterson '166: Abstract ("The composition of the system is particularly effective for delivering medication systemically to a host animal over a prolonged period of time after being surgically implanted or injected subcutaneously."); col. 2:3-5 ("The delivery system is usually implanted subcutaneously by injection or incision in an animal, including the human body."); col. 2:24-27 ("The time-release chemical delivery systems of this invention are intended for implantation, either surgically or by injection in animals, including humans."); col. 11:23-24 ("A time release chemical delivery system for implantation in animal host comprising . . .").

Schwartz '823: Abstract ("The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen. The stent is especially useful for repairing an injury to blood vessels caused during angioplasty procedures."); col. 2:16-24 ("It is therefore an object of the present invention to provide a stent having longitudinal flexibility which allows it to conform to curves and variations in body lumens. . . . It is also an object of the present invention to provide a stent capable of delivering therapeutic agents to a blood vessel."); col. 2:29-37 ("In a radially expandable stent for implantation within a body lumen, the stent having a generally cylindrical body with open proximal and distal ends, the cylindrical body comprising a plurality of metal elements joined to permit flexing of the cylindrical body along its longitudinal axis to permit the

¹ Defendants have included claim preambles in their claim chart for completeness, but do not contend that such preambles constitute claim limitations.

stent to conform to a curved body lumen, the improvement of the present invention comprises a polymeric film extending between the metal elements."); col. 2:40-44; col. 2: 49-53; col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:48-54; col. 3:58-col. 4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof."); col. 6:17-38; col. 8:8-9 ("The stent of claim 1 wherein the film comprises a therapeutic substance.").

Scott '928: Fig. 3; Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14 ("The present invention satisfies this need by providing a separate sleeve to encompass the stent and serve as a local drug delivery device to prevent thrombosis."); col. 4:53-55 ("The present invention satisfies this need by providing a separate sleeve to encompass a stent to locally administer drugs to prevent restenosis."); col. 4:58-68 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 5:26-29; col. 6:49-55 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject."); col. 8:23-54; col. 9:12-16 ("In addition, polymer-drug films which prevent thrombosis in the baboon and pig AV shunt system can be studied following stent-film placement in carotid, superficial femoral and coronary arteries following balloon injury of those vessels."); col. 10:24-33 ("In combination, a hollow tubular stent having a predetermined length and a separate sheath removably encompassing at least a portion of said hollow tubular stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug."); col. 10:45-47 ("A method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath of claim 2 into a vessel of the subject.");

col. 10:55-57 ("8. A method of promoting vascular cell growth in a subject comprising inserting a stent encompassed by the sheath of claim 6 into a vessel of a subject."); col. 11:1-3 ("11. A method of inhibiting vascular cell growth in a subject comprising inserting a stent encompassed by the sheath of claim 9 into a vessel of the subject."); col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:12-20 ("Stents are typically implanted within a vessel in a contracted state and expanded when in place in the vessel in order to maintain patency of the vessel to allow fluid flow through the vessel. Ideally, the implantation of such stents is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:42-50; col. 1:50-56 ("The stent can be used in coronary arteries or any other part of the vasculature or other body lumen where mechanical opening force is necessary or desirable to keep the vessel open or to maintain the stent flush against the lumen wall, and where an anti-restenosis, anti-proliferative or other types of therapeutic drug or agent is to be simultaneously positioned and diffused."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 1:64-2:2; col. 4:25-46; col. 5:4-9 ("The primary function of the sheet of polymeric material is to deliver therapeutic agents or drugs to help prevent thrombosis and/or restenosis."); col. 5:18-25; col. 5:49-6:25; col. 7:56-62 ("The elastic material attached over the coil of polymeric material helps keep the coil of drug loaded material snug on the stent structural member before it is expanded, and guides its linear expansion during inflation of a balloon dilatation catheter used for deployment of the stent and polymeric drug loaded material in the vasculature or other body lumen of a patient."); col. 9:3-18; col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:52-62 ("The invention provides prostheses which may be inserted into a lumen of a body and fixed to the lumen wall adjacent an area needing treatment. . . . [T]he methods and devices of the invention are also suited to treatment of any body lumen, including vas deferens, ducts of the gall-bladder, prostate gland, trachea, bronchus and liver or any other lumen of the body where medication cannot be applied without a surgical procedure."); col. 2:7-16 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:25-27 ("The current invention contemplates the usage of any prosthesis which elutes drugs locally to treat a lumen in need of repair."); col. 6:36-38; col. 11:47-48; 11:50-53.

Berg '354: Page 2:3-4 ("This invention relates to intravascular stents for treatment of injuries to blood vessels and particularly to stents having a framework onto which a therapeutic substance or drug is applied."); p. 2:14-18 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen. Examples of stents which have been successfully applied over a PTCA balloon and radially expanded at the same time as the balloon expansion of an affected artery include the stents disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) which are incorporated herein by reference in their entirety."); p. 3:16-18 ("In operation, the stent made according to the present invention can deliver drugs to a body lumen by introducing the stent transluminally into a selected portion of the body lumen and radially expanding the stent into contact with the body lumen."); p. 3:29-31; p. 5:53-6:1; p. 6:6-11; p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Abstract ("A stent made of biodegradable material includes a drug that is released at a rate controlled by the rate of degradation of the biodegradable material."); col. 2:55-56 ("The present invention includes a biodegradable stent for insertion into a lumen of a vessel in a living being."); col. 3:9-11 ("The stent releases drugs into a tubular vessel having a lumen in a living being."); col. 4:46-64; col. 5:11-20; col. 6:9-28; col. 6:65-7:1; col. 7:32-3.

Ding '536: Col. 1:29-32 ("The invention is particularly in terms of coatings on therapeutic expandable stent prostheses for implantation in body lumens, e.g., vascular implantation."); col. 1:34-45; col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 5:10-56; col 13:13-26 ("A medical device having at least a portion which is implantable into the body of a patient, wherein at least a part of the device portion is metallic and at least part of the metallic device portion is covered with a coating for release of at least one biologically active material . . .").

Dinh '227: Abstract ("An intraliminal stent comprising fibrin and an elutable drug is capable of providing a treatment of restenosis."); col. 1:11-13 ("This invention relates to a method for lessening restenosis of body lumens and to intraliminal stents having anti-thrombosis and anti-restenosis properties."); col. 1:32-35; col. 2:35-37; col. 2:62-66; col. 6:19-22 ("The drug, fibrin and stent can then be delivered to the portion of the body lumen to be treated where the drug may elute to affect the course of restenosis in surrounding luminal tissue."); col. 8:20-27 ("The term 'stent' herein means any device which when placed into contact with a site in the wall of a lumen to be treated, will also place fibrin at the lumen wall and retain it at the lumen wall. This can include especially devices delivered percutaneously to treat coronary artery occlusions and to seal dissections or aneurysms of splenic, carotid, iliac and popliteal vessels."); col. 12:24-28.

Domb '055: Abstract ("Devices are provided having a polymer coating incorporating compounds inhibiting inflammation and infection, along with subsequent tissue growth onto and around the device. Preferred embodiments include catheters, tubes and implants that abut tissue following implantation into the body . . ."); col. 1:12-18 ("This invention relates to invasive medical devices for delayed/sustained release of pharmaceutical compositions from a polymer that is coated or incorporated into the devices. The purpose of the coating or delivery system on these devices is to reduce, control or even prevent the inflammation and infection that occur with prolonged use of these devices."); col. 4:15-17; col. 4:22-32; col. 5:24-6:18; col. 6:24-26; col. 11:27-38 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Abstract; col. 1:64-2:5; col. 2:9-21; col. 2:48-65; col. 3:55-67; col. 16:16-22; col. 31:62-64; col. 36:21-31; col. 37:34-38; col. 37:66-38:9; col. 49:27-31.

Hunter '981: Col. 1:12-17 ("The present invention relates generally to compositions and methods for treating cancer and other angiogenic-dependent diseases, and more specifically, to compositions comprising anti-angiogenic factors and polymeric carriers, stents which have been coated with such compositions, as well as method for utilizing these stents and compositions."); col. 3:39-45; col. 4:14-5:36; col. 7:12-16 ("Fig. 13 is an illustration of a representative embodiment of hepatic tumor embolization. Fig. 14 is an illustration of the insertion of a representative stent coated with an anti-angiogenic composition."); Fig. 13; Fig. 14; col. 12:23-35; col. 16:31-56; col. 17:63-18:7 ("[T]he anti-angiogenic compositions of the present invention may be formed as a film. . . . Such films are preferably flexible with a good tensile strength . . . and has controlled permeability."); col. 22:3-7; col. 23:6-13 ("[M]ethods are provide for expanding the lumen of a body passageway, comprising inserting a stent into the passageway, the stent having a generally tubular structure, the surface of the structure being coated with an anti-angiogenic composition . . . such that the passageway is expanded."); col. 23:46-51; col. 24:45-51; col. 24:66-25:5; col. 25:24-29; col. 25:48-54; col.84:63-85:4; col. 86:56-59; col. 87:11-22; col. 88:19-26; col. 87:1-2.

Kinsella '608: Col. 6:8-12 ("Each of the aforementioned applications may also be amendable to selective, localized application of sustained-release preparations of taxol (or other microtubule-stabilizing agent) which would enable high dosage local drug delivery with little systemic toxicity."); col. 11:14-24 ("Ultimately, local sustained-release delivery systems may offer the best solution to prevent restenosis post-angioplasty, enabling high local concentrations of drug delivery and essentially eliminating problems of systemic toxicity. Drug delivery systems that can be valuable include drug-impregnated polymer-coated metallic stents [and] biodegradable drug-eluting polymer stents . . .").

Kowligi '782: Abstract ("The elastomeric coating is made of polyurethane or another biocompatible non-porous elastomers and precludes tissue ingrowth into the outer cylindrical wall, minimizes suture hold bleeding, and increases suture retention strength, while reducing the incidence of serous weepage."); col. 1:18-26 ("The present invention relates generally to prosthetic vascular grafts for implantation within the vascular system of a patient, and more particularly, to a prosthetic vascular graft made from expanded, porous polytetrafluoroethylene (PTFE) tubing that is fabricated to retain the porous inner cylindrical wall of conventional PTFE vascular grafts, but wherein the outer cylindrical wall of the PTFE tube is rendered non-porous over at least a portion of its length."); col. 4:16-27; col. 10:18-24; col. 10:33-42; col. 10:51-59.

Lambert '922: Abstract; col. 2:16-35 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); col. 2:62-67 ("In accordance with yet another embodiment of the present invention, there is provided a method for the localized delivery of biologically active compounds to a subject. This invention method comprises implanting the above-described delivery system at a site where the targeted release of said biologically active compound is desired."); col. 3:8-12; col. 3:29-32; col. 3:50-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected)."); col. 7:29-32; col. 10:54-56; col. 12:40-42; col. 13:10-12.

Lambert '308: Abstract; p. 3:10-31 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); p. 4:25-31 ("In accordance with yet another embodiment of the present invention, there is provided a method for the localized delivery of biologically active compounds to a subject. This invention method comprises implanting the above-described delivery system at a site where the targeted release of said biologically active compound is desired."); p. 6:15-20 ("Substrates suitable for use in the practice of the present invention include metallic stents, such as vascular, biliary or ureteral stents, heart valves, metallic prostheses, prosthetic joints, pacemakers, catheters, balloon coatings, ocular implants, contact lenses, and the like."); p.6:21-28 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected)."); claim 1:1-4; claim 19:1-3; claim 20; claim 27:1-5.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8.

Mitchell '711: Col. 3:24-31 ("This invention provides a method of preventing or treating hyperproliferative vascular disease in a mammal in need thereof by administering an antiproliferative effective amount of a combination of rapamycin and heparin to said mammal . . . via a vascular stent impregnated with a combination of rapamycin and heparin."); col. 7:16-20 ("Rapamycin in combination with heparin can be administered intravascularly or via a vascular stent impregnated with rapamycin in combination with heparin, during balloon catheterization to provide localized effects immediately following injury."); col. 7:56-8:7; col. 8:22-23; col. 8:39-42; col. 8:49-56.

Morris '781: Col. 3:45-50 ("This invention provides a method of preventing or treating hyperproliferative vascular disease in a mammal in need thereof by administering an antiproliferative effective amount of rapamycin to said mammal . . . via a vascular stent impregnated with rapamycin."); col. 11:41-45 ("Rapamycin, alone or in combination with mycophenolic acid can be administered intravascularly or via a vascular stent impregnated with rapamycin, alone or in combination with mycophenolic acid, during balloon catheterization to provide localized effects immediately following injury."); col. 12:29-35 ("A method of treating restenosis in a mammal . . . which comprises administering an antirestenosis effective amount of rapamycin to said mammal . . . via a vascular stent impregnated with rapamycin."); col. 12:36-42.

Morris '182: Page 3:24-27 ("This invention provides a method of preventing or treating hyperproliferative vascular disease in a mammal in need thereof by administering an antiproliferative effective amount of rapamycin to said mammal . . . via a vascular stent impregnated with rapamycin."); p. 7:27-29 ("Rapamycin, alone or in combination with mycophenolic acid can be administered intravascularly or via a vascular stent impregnated with rapamycin, alone or in combination with mycophenolic acid, during balloon catheterization to provide localized effects immediately following injury."); p. 7:57-8:1 ("Use as claimed in Claim 1 in which the medicament is adapted for administration . . . via a vascular stent impregnated with rapamycin."); p. 8:8-9 ("A use or product according to any one of Claims 1 to 4 wherein the hyperproliferative vascular disease is selected from intimal smooth muscle cell hyperplasia, restenosis, and vascular occlusion."); col. 8:15-16.

Myler '563: Abstract; col. 1:11-12 ("The present invention relates to cardiovascular stents which can be inserted into a body lumen."); col. 2:20-22; col. 2:53-58; col. 3:13-15; col. 4:56-57; col. 5:24-26 ("One purpose of the temporary stent is to modify the healing response to prevent re-occlusion of the artery (restenosis)."); col. 12:28-33; 12:63-65; col. 19:18-30 ("A tubular stent for implantation within a body lumen . . ."); col. 20:33-49; col. 20:51-52.

Palmaz '417: Abstract; col. 1:17-23 ("The invention relates to an expandable intraliminal graft for use within a body passageway or duct and, more particularly, expandable intraliminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease; and a method and apparatus for implanting expandable intraliminal grafts."); col. 4:25-

37; col. 5:1-20; col. 5:26-43; col. 6:20-54; col. 11:3-34; col. 13:20-40; col. 14:39-59; col. 15:19-40; col. 15:53-16:5; col. 16:18-34; col. 16:43-63.

Aebischer '486: Abstract; Fig. 1; col. 3:19-23; col. 3:56-63; col. 5:29-43; col. 6:39-40; col. 8:1-30; col. 9:18-10:3.

Folkman '560: Col. 2:43-68; col. 3:18-23; col. 6:61-7:2; col. 10:11-14; col. 11:41-47; col. 11:56-12:20.

Schiraldi '243: Abstract; col. 1:8-21; col. 2:21-25 ("It is an object of this invention to provide an extruded film that is an effective and convenient intra-oral drug delivery system and method for applying and delivering controlled dosages of therapeutic agents into the oral cavity."); col. 2:30-51; col. 9:36-55.

Valentini '029: Abstract ("Medical devices employing semipermeable materials, such as acrylic copolymers, polyurethane isocyanate, and other biocompatible semipermeable polymers, are disclosed for use as guidance channels in regenerating nerves."); col. 2:29-57; col. 6:14-42.

Greco '135: Col. 3:8-19 ("An object of the present invention is to provide improved surfactant-modified implantable devices having a drug, including antibiotics, antithrombogenic agents, thrombolytic agents, disinfectants, etc., bound to the surface thereof."); col. 3:48-4:1; col. 9:10-12; col. 9:25-26.

Bawa '279: Col. 2:8-15 ("Another object is to provide a sustained-release polymeric hydrogel dosage form that is useful for topical, systemic or transdermal administration of medicinal agents, particularly ophthalmic drugs. A further object is to provide a polymeric matrix which is moldable to any desired shape, with moldability to the shape of the cornea of the eye being of major interest."); col. 8:50-53.

Wood '066: Abstract ("A controlled-release bandage containing therapeutic agents in a poly(vinyl alcohol) cryogel is disclosed. The bandage may include . . . hydrophobic particles to further insure controlled and constant release of therapeutic agents."); col. 2:56-66 ("Bandages comprising cryogel and therapeutic agents are used to provide a protective covering and to provide a controlled and uniform administration of therapeutic agents to sites of trauma such as wound, thermal or chemical burns, ulcers, lesions or surgical sites. Cryogel bandages may include . . . particles having hydrophobic properties, which absorb the therapeutic agent and release it in an uniform and controlled manner."); col. 2:67-3:10; col. 23:4-11.

Strecker '746: Abstract ("The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:56-2:2; 2:12-15; col. 2:21-32; col. 5:34-54; col. 6:59-62; col. 7:16-35; col. 8:19-10:19.

Lambert '246: Abstract; col. 2:15-34; col. 3:55-4:35; col. 10:45-61; col. 11:34-12:12; col. 12:15-52.

Bellamkonda '029: Abstract; Fig. 6; col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 4:9-14; col. 10:64-11:13; col. 11:33-40; col. 12:17-25; col. 19:33-22:37.

Dayton '382: Abstract ("A minimally invasive bioactivated endoprosthesis device for vessel repair. The device comprises a stent which is formed from metal or polymers into a predetermined shape which includes a plurality of holes . . . to provide a desired bending modulus."); col. 1:9-17 ("The present invention relates to an improved percutaneously inserted endoprosthesis device which is permanently or temporarily implanted within a body vessel, typically a blood vessel."); col. 3:62-4:17; col. 5:50-53; col. 8:4-33.

Burt '036: p. 4:19-33; p.10:17-25; p.14:9-27 ("As noted above, anti-angiogenic compositions of the present invention comprise an anti-angiogenic factor and a polymeric carrier. In addition to the wide array of anti-angiogenic factors and other compounds discussed above, anti-angiogenic compositions of the present invention may include a wide variety of polymeric carriers, including for example both biodegradable and non-biodegradable compositions."); p.21:2-4; 21:25-22:6.

Goldin '568: Abstract; col. 1:43-62; col. 2:1-6 ("In other instances, among them the release from the walls of cylindrical nerve guide tubes of trophic factors believed to aid nerve regeneration . . . it may be desirable for such an implantable delivery device to slowly decompose in vivo."); col. 2:24-29; col. 4:48-57 ("A preferred embodiment entails implantation of the device at or near the target of the desired therapeutic effect."); col. 10:55-58; col. 11:6-9; col. 23:6-26:5.

Palmaz '665: Abstract ("An expandable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 1: 11-17; col.2:64-3:7.

Palmaz '762: Abstract ("An expandable and deformable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 1:19-25; col. 4: 6-19.

Palmaz '337: Abstract ("An expandable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 1: 24-30; col. 3: 1-12.

Zaffaroni '254: Abstract ("A drug delivery device for administering a drug at a controlled rate for a prolonged period of time to produce a local or systemic physiological or pharmacological effect is comprised of a wall surrounding a reservoir containing a drug."); col. 4: 15-17 ("FIG. 4 is a side, fragmentary view depicting an anal drug delivery device of the invention for releasing drug in a body orifice."); col. 4: 21-28; Figures 4 and 6; col. 5: 65-68; col. 7: 1-5.

Aebischer: p. 283 (disclosing use of ethylene-vinyl acetate copolymer), p. 284-5 (disclosing implantation into human or animal tissue to promote nerve regeneration).

Dev: p. 273-74 (disclosing implantation of a polymer-coated stent capable of releasing treatment material).

Claim 1 [1B] (cont'd): a layer of flexible material that is minimally porous to macromolecules, said layer having a first and second major surface,

Where Found in the Prior References

Schwartz '823: Abstract ("The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen."); Figs. 6-9, 13, 15; col. 2:29-40; col. 2:49-53; col. 3:58-61 ("The improvement of the present invention includes applying to the above-mentioned type of stent a flexible or elastomeric polymeric film which extends between the metal elements."); col. 3:64-4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof."); col. 6:17-20; col. 6:59-62 ("The flexible film can be applied as a sheath to the metal stent elements after which the stent can be compressed, attached to a catheter, and delivered through the body lumen to a desired location."); col. 7:25-8:11 ("The resulting stent has microcapsules containing one therapeutic substance on the inside (and able to contact blood once implanted in a blood vessel) and microcapsules containing a second therapeutic substance on the outside (and able to contact the vessel wall when implanted in contact with the vessel wall).").

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); Fig. 3; col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-29; col. 5:34-6:29; col. 6:37-41; col. 6:41-45 ("Modifications of the polymer coating include a ring that encompasses the proximal portion of the stent, single or multiple strips that cover a portion of the stent, or a

polymer coating with perforations."); col. 7:55-59; col. 8:23-54 ("Ethylene vinyl acetate copolymer (EVA) (Catalog #34,691-8) was obtained from Aldrich Chemical Company, Inc. (Milwaukee, Wis.); col. 10:24-33; col. 12:1-6; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow Controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Fig. 3; col. 1:7-10 ("This invention relates generally to expandable intraliminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 1:64-2:2 ("The polymer material can be a thermoplastic or an elastomer, for example, so that the film can stretch or deform radially when the stent structural member is expanded. The film of polymer material can be formed as a solid sheet, or can incorporate holes of various sizes and shapes to promote rapid endothelialization."); col. 4:15-24; col. 4:25-46; col. 4:47-5:3; col. 5:4-9; col. 5:49-6:25 ("The polymeric material is preferably selected from thermoplastic and elastomeric polymers. . . . In another currently preferred embodiment, the polymeric material can be ethylene vinyl acetate (EVA) . . ."); col. 6:26-65; col. 6:66-col.7:7; col. 7:23-42; col. 7:63-65; col. 8:12-57; col. 9:5-12; col. 10:12-30.

Wolff '208: Col. 2:7-16 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); 2:28-30 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 6:59-62 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously. The polymer may be biostable or bioabsorbable. If biostable, the drug would diffuse out of the polymer."); col. 6:64-67 ("The variations of design shown in the embodiments of Figs. 1 and 2 show that the prosthesis of the invention must be secured against a lumen wall and must carry a drug-eluting polymer."); col. 7:59-61; col. 9:23-33 ("That layer may be a simple barrier which limits diffusion of drugs in the polymer. In that event, the smaller molecules could elute out immediately, while larger compounds would not elute until later when the layer has biodegraded."); col. 11:50-53 ("(b) a body including a plurality of support elements forming an open-ended, radially expandable, self-supporting tubular structuring having an interior surface and an exterior surface."); col. 12:1-15; col. 12:37-40 ("8. The device of claim 1 also comprising a barrier coating of polymeric material on the drug-containing filament to limit the rate of drug elution.").

Berg '354: Page 2:43-54 ("Viewed from a further aspect the invention provides the use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug-eluting surface coating."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:29-31 ("Also, stents made with biostable or bioabsorbable polymers such as poly(ethylene terephthalate), polyacetal, poly(lactic acid), poly(ethylene oxide)/poly(butylene terephthalate) copolymer could be used in the present invention. "); p. 3:33-34 ("Both the inner and outer surfaces of the stent may be provided with the coating according to the present invention."); Table 1; p. 4:5-24; p. 6:6-11; p. 6:15; p. 6:24-35; p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Col. 2:16-17; col. 3:21-25 ("The tubular main body includes an outer surface and inner surface. The outer surface of the main body faces an inner surface wall of the vessel. The inner surface of the stent faces a stream flowing through the lumen as shown in cross section in Fig. 2."); col. 4:1-5 ("In one embodiment, the main body includes a film that is preferable combined with the plurality of fibers disposed around the main body. The film combined with the plurality of fibers defines the outer surface of the main body."); col. 4:15-16 ("Preferable, the main body of the stent includes a film covering the inner surface."); col. 4:19-22 ("Additionally, the present invention includes an embodiment where the inner surface and the outer surface of the main body are separated by at least one interior film layer."); col. 5:23-33 ("For instance, in one embodiment, the film and fibers covering the inner surface of the main body of the biodegradable stent The film covering the outer surface along with the plurality of fibers"); col. 4:46-64; col. 5:11-20; col. 6:49-59; col. 7:27-29; Fig. 2.

Ding '536: Abstract ("The coating includes a relatively thin layer of biostable elastomeric material containing an amount of biologically active material, particularly heparin, dispersed in the coating in combination with a non-thrombogenic surface."); col. 1:24-29 ("The present invention relates generally to providing biostable elastomeric coatings on the surfaces of implants which incorporate biologically active species having controlled release characteristics in the coating particularly to providing a non-thrombogenic surface during and after timed release of the biologically active species."); col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 5:10-56 ("Polymers generally suitable for the undercoats or underlayers include silicones (e.g., polysiloxanes and substituted polysiloxanes), polyurethanes, thermoplastic elastomers in general, ethylene vinyl acetate copolymers, polyolefin elastomers, polyamide elastomers, and EPDM rubbers. The above-referenced materials are considered hydrophobic with respect to the contemplated environment of the invention."); col. 12:62-13:2; col. 13:13-26; col. 13:37-40; col. 14:5-17; col. 14:22-34.

Dinh '227: Figs. 1, 9, 10; col. 2:51-54 ("To accomplish this while not affecting the strength of the overall fibrin stent structure, a first layer is applied to a stent body, the first layer incorporating a polymer and the therapeutic substance."); col. 2:62-66 ("The inclusion of a polymer in intimate contact with a drug on the underlying stent structure allows the drug to be retained on the stent in a resilient matrix during expansion of the stent and also slows the administration of drug following implantation."); col. 3:10-14; col. 3:25-38; col. 5:3-7; col. 5:44-55; col. 5:56-57; col. 6:13-19 ("In U.S. Pat. No. 4,548,736 issued to Muller et al., a dense fibrin composition is disclosed which can be a bioabsorbable matrix for delivery of drugs to a patent. Such a fibrin composition can also be used in the present invention by incorporating a drug or other therapeutic substance useful in diagnosis or treatment of body lumens to the fibrin provided on the stent."); 6:50-56 ("Alternatively . . . a dense fibrin composition suitable for drug delivery can be made without the use of microcapsules by adding the drug directly to the fibrin followed by compression of the fibrin into a sufficiently dense matrix that a desired elution rate for the drug is achieved."); col. 6:62-67; col. 7:10-13; col. 7:56-64 ("In another embodiment of the invention, the coating of polymer and drug on the stent is achieved by forming a first fibrin layer on the stent body which incorporates the therapeutic substance and then applying a second layer of fibrin."); col. 8:52-60 ("Fig. 2 shows an alternative stent in which a fibrin film has been affixed to the underlying metallic framework by affixing it to the stent . . ."); col. 8:64-9:3; col. 12:24-28; col. 12:38-50.

Domb '055: Abstract ("Devices are provided having a polymer coating incorporating compounds inhibiting inflammation and infection, along with subsequent tissue growth onto and around the device. . . . Preferred polymeric coating are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); col. 1:12-15 ("This invention relates to invasive medical devices for delayed/sustained release of pharmaceutical compositions from a polymer that is coated or incorporated into the devices."); col. 3:54-57 ("In the preferred embodiments, these have utilized bioerodible polymers as the matrix for the drug to be released, usually as a function of diffusion and erosion of the polymer."); col. 4:22-36; col. 5:24-37; col. 5:41-45; col. 5:48-6:1; col. 6:24-26 ("Examples of suitable polymers include ethylene vinyl acetate, polyurethane, silicones, hydrogels, polyurethane, and polyvinyl chloride."); col. 7:10-20; col. 7:40-52; col. 9:15-30; col. 9:55-10:2; col. 10:21-52; col. 10:60-11:11; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 11:36-38 ("The medical device of claim 1, wherein the polymer is selected from the group consisting of polyurethane, ethylene vinyl acetate, silicones, hydrogels, and polyvinyl chloride."); col. 11:39-44; col. 12:11-22; col. 12:23-25; col. 12:26-31; col. 12:32-42.

Fox '096: Abstract ("A method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers, and antimicrobial agents . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention,

there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 2:48-65; col. 3:55-67 ("The polymeric coating agent component of the coating vehicle of the present invention is selected from the group consisting of biomedical polyurethanes, biomedical silicones, biodegradable polymers and combinations thereof."); col. 3:55-67; col. 19:11-16; col. 31:62-64.

Hunter '981: Fig. 14B; col. 1:12-17; col. 3:42-45 ("Within one aspect of the present invention, compositions are provided (anti-angiogenic compositions) comprising (a) an anti-angiogenic factor and (b) a polymeric carrier."); col. 3:53-61; col. 12:23-25 ("As noted above, the present invention provides compositions comprising an anti-angiogenic factor, and a polymeric carrier."); col. 16:31-56; col. 17:63-18:7 ("[T]he anti-angiogenic compositions of the present invention may be formed as a film. . . . Such films are preferably flexible with a good tensile strength . . . and has controlled permeability."); col. 22:3-7; col. 22:40-64; col. 22:54-58; col. 47:58-49:7; col. 52:4-8; col. 69:19-62; col. 84:62-86:24; 86:56-59; col. 87:11-22; col. 88:19-26.

Kowligi '782: Abstract ("The elastomeric coating is made of polyurethane or another biocompatible non-porous elastomers and precludes tissue ingrowth into the outer cylindrical wall, minimizes suture hold bleeding, and increases suture retention strength, while reducing the incidence of serous weepage."); Figs. 2 & 3; col. 1:18-26; col. 1:28-41; col. 1:42-64; col. 2:15-20; col. 2:38-47; col. 2:53-59; col. 2:60-3:4 ("PTFE tube 32 includes an inner cylindrical wall and an opposing outer cylindrical wall. As shown in Fig. 2, outer cylindrical wall is coated entirely around its circumference by a uniformly thick coating of a biocompatible elastomer."); col. 3:27-38; Figure 3; col. 4:1-5; col. 4:16-27 ("In regard to elastomeric coating 38 shown in Fig. 2, such elastomeric coating is selected to be a biocompatible elastomers and may be selected from the group consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 4:37-39 ("The elastomeric coating should also be sufficiently non-porous to preclude serous weepage and inhibit tissue ingrowth therethrough."); col.4:64-66; col. 5:4-7; col. 7:49-8:9; col. 8:38-44; col. 9:65-10:6; col. 10:18-24; col. 10:33-42; col. 10:43-50; col. 10:51-59; col. 10:60-67.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 2:16-35; col. 2:40-50; col. 3:8-12; col. 3:29-32; col. 3:55-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); col. 5:57-61; col. 7:29-32; col. 10:57-64; col. 11:49-51; col. 11:65-12:13; col. 12:43-64; col. 13:13-19.

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p. 3:10-31 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); p. 4:2-12; p. 6:21-28 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); p. 10:17-21; claim 1:1-14; claim 8:1-5; claim 10:1-3; claim 11; claim 22; claim 23:1-14; claim 19:4-31.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8.

Myler '563: Figs. 1, 2, 13; col. 2:10-13; col. 3:13-15; col. 3:52-54; col. 4:30-43 ("In a preferred embodiment, the interior and exterior walls of stent 10 are enclosed in a thin polymeric envelope. . . . Suitable envelope materials include elastic materials such as latex and others that can be readily selected by one of skill in the art."); col. 4:53-56; col. 5:1-16; col. 5:39-41 ("For the above reasons, even the expanded pores for drug delivery should be small enough to maximize or prevent cell penetration, but large enough for drug delivery."); col. 12:11-13; col. 12:19-23; col. 12:28-33 ("Suitable materials include elastomeric polymers or natural rubber (latex). . . . Polymeric stents can be provided with relatively fluid impenetrable walls, or porous walls such as to allow drug delivery, as will be apparent to one of skill in the art."); col. 12:54-62; col. 12:63-65 ("Suitable coating materials include elastic materials such as polyethylene or PET or other materials that can be readily selected by one of skill in the art."); col. 18:51-19:9; col. 19:18-30; col. 19:31-32; col. 19:61-63; col. 20:51-57.

Palmaz '417: Fig. 1A, 1B, 3, 5, 6, 8; Col. 5:66-68 ("Figs 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon;"); col. 11:3-14 ("Examples of a suitable biologically compatible coating would be porous polyurethane, Teflon™ or other conventional biologically inert plastic materials."); col. 11:3-34 ("Examples of biologically compatible coatings would include coatings made of absorbable polymers such as those used to manufacture absorbable sutures. Such absorbable polymers include polyglycoides, polyacoides, and copolymers thereof.").

Tice '330: Col. 3:20-33 ("Suitable wall forming materials include polystyrene, ethylcellulose, cellulose acetate, hydroxyl propylmethylcellulose phthalate, cellulose acetate, dibutylaminohydroxypropyl ether, polyvinylbutyral, polyvinyl formal, poly(meth)acrylic acid ester, polyvinylacetal-diethylamino acetate, 2-methyl-5-vinyl pyridine methacrylate-methacrylic acid copolymer, polycarbonate, polyesters, polypropylene, vinylchloride-vinylacetate copolymer, polysaccharides, glycerol distearate, and the like. A preferred group of polymeric wall forming

materials includes those which are biodegradable such as aliphatic polyesters including polylactide, polyglycolide, polycaprolactone and copolymers thereof."); col. 8:38-51.

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); Figs. 1 & 2; col. 3:7-18; col. 3:56-63; col. 4:31-34 ("The outer membrane surface is nonporous, while porous inner membrane surface allows for the diffusion therethrough of active factor 26."); col. 5:18-28 ("In a preferred embodiment of the invention, the outer surface of the membrane is impermeable to solutes of any size, while the inner membrane surface contains pores [that] enable the active factors to diffuse out of the membrane and into the lumen of the channel."); col. 6:17-22 ("The layering procedure allows deposition of an impermeable coat on the outer surface of the device, insuring that the active factors incorporated into the membrane walls will be inhibited from diffusing through the external surface, and will diffuse only through the inner membrane surface into the lumen of the channel."); col. 6:54-61; col. 9:18-10:3.

Folkman '560: Col. 2:43-68 ("A biocompatible plastically deformable polymer matrix . . . substantially impermeable to a macromolecule"); col. 3:18-23 ("The polymer matrixes, which are suitably used in the present invention, are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:36-51 ("Typical polymeric material suitable for forming the matrix . . . include . . . alkylene-vinyl acetate copolymers . . . crosslinked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:52-4:26 ("In the presently preferred embodiment the polymeric materials useful for forming the matrix are the ethylene vinyl ester copolymers of the general formula . . ."); col. 11:56-12:20.

Cohen '496: Col. 3:26-45 ("The polymer matrices . . . are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 9:40-10:17; col. 10:18-32.

Schiraldi '243: Col. 1:8-21 ("The extruded film drug delivery system of the present invention, which has incorporated therein the medicament to be dispensed, is so thin and flexible when wet as to be unobtrusive to the patient after it has been properly positioned and placed in the mouth."); col. 1:58-60; col. 2:30-51; col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. . . . The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 9:36-55; col. 10:12-18; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Valentini '029: Abstract ("Medical devices employing semipermeable materials, such as acrylic copolymers, polyurethane isocyanate, and other biocompatible semipermeable polymers, are disclosed for use as guidance channels in regenerating nerves. . . . The guidance materials are chosen such that they are capable of allowing the diffusion of nutrients and other metabolites to the regenerating nerve site while excluding fibroblasts and other scar-forming cells."); Fig. 3; col. 2:29-57 ("It has been discovered that the repair of severed or avulsed nerves can be greatly enhanced by the use of selectively permeable polymeric materials as nerve guidance channels. . . . The devices can be formed from various polymeric materials, such as acrylic copolymers, polyvinylidene fluoride or polyurethane isocyanate Preferable, the materials allow passage therethrough of solutes having a molecular weight of about 100,000 daltons or less. . . . The nerve guidance channels of the present invention are also preferably designed to retain nerve growth factors secreted at the anastomatic site or seeded therein, as well as retain any luminal matrix material placed inside the guidance channels."); col. 2:58-3:14; col. 4:46-59; col. 5:13-32 ("The success rate and quality of peripheral nerve regeneration was dramatically enhanced through the use of a semipermeable material."); col. 5:33-41; col. 5:42-6:12 ("The permselective characteristics of the inner membrane allow the exchange of nutrients, while concentrating growth factors released by the nerve and excluding scar-forming cells."); col. 6:14-24; col. 6:31-42.

Greco '135: Col. 3:48-4:1 ("These devices will consist of organic polymers and/or metallic materials including: . . . polyethylene . . . elastomeric organosilicon polymers, such as polysiloxanes, e.g. Silastic ®").

Aebischer '627: col. 3:57-4:3 ("The polymeric insert includes pores having a molecular weight exclusion of from about 1 kD to about 1,000 kD, but preferably from about 25kD to about 100 kD."); col. 4:11-27 ("The terms 'semipermeable' is used herein to describe biocompatible membranes that allow the diffusion therethrough of molecules having a relatively low molecular weight, while excluding the passage of those having a relatively high molecular weight. . . . The semipermeable membrane can be made of various polymeric compositions such as polyvinylchloride, polyacrylonitrile, polyvinylidene fluoride, polystyrene, polymethylmethacrylate, polysulfone, and acrylic copolymers."); col. 7:57-8:14 ("In this embodiment, a semi-permeable membrane functions as a protective cell culture device for the neurotransmitter-secreting cells. The pores of the membrane should be large enough to enable the exchange of metabolites with body fluids, and to permit the diffusion therethrough of neurotransmitter produced by the cells therein, but are small enough to bar the passage therethrough of larger elements deleterious to the cells."); col. 13:31-48; col. 13:66-68; col. 14:1-2; col. 14:22-28; col. 14:54-56.

Bawa '279: Col. 6:50-57 ("Alternatively, a two layer system may be formed having one layer as polymer plus drug and the other layer as drug-free polymer.").

Wood '066: Abstract ("A controlled-release bandage containing therapeutic agents in a poly(vinyl alcohol) cryogel is disclosed. The bandage may include . . . hydrophobic particles to further insure controlled and constant release of therapeutic agents."); col. 2:56-66; col. 23:4-11.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); Figs. 4, 7, 8; col. 1:63-2:2; col. 2:12-15 ("The present invention on the other hand exploits a wrapping material that plastically deforms as it expands . . ."); col. 2:21-32; col. 2:33-38; col. 2:59-64; col. 3:7-16; col. 3:27-33 ("The lining can to advantage be made of polymers or compounds thereof."); col. 3:51-62; col. 3:63-4:31 ("It can be of advantage for the lining to be of several layers, each impregnated with different medications. . . . It has also been demonstrated practical for the inner layer of the lining to be impregnated with antithrombotics and the outer with antiproliferatives and/or other medicational substances."); col. 5:18-20 ("Fig. 4 is a view similar to that of Fig. 2 of an endoprosthesis with a multiple-layer lining and with its ends coated with medication."); col. 5:34-41 ("The endoprosthesis . . . is completely enclosed in an inner lining component and an outer lining component."); col. 5:49-54 ("The thread itself in an endoprosthesis of the type illustrated in Fig. 3 can also be wrapped in a coat of medicated and biodegradable wrapping material. . . . The prosthesis can of course alternatively be enclosed in a flexible-tubular coat."); col. 5:55-64; col. 6:30-44; col. 6:50-55; col. 6:59-62; col. 7:16-35; col. 7:48-65; col. 8:4-8; col. 8:10-10:19.

Lambert '246: Abstract ("Thus, a polyurethane coating is applied to a prosthetic article, the coating then swelled . . . so that substantial quantities of biologically active compounds can be incorporated within the interstices of the polymer."); col. 2:15-34; col. 2:40-49; col. 2:53-65; col. 3:55-4:35 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility to as to enable the application of a stable coating onto substrate (i.e. the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected)."); col. 10:45-67; col. 11:34-59; col. 12:15-41.

Bellamkonda '029: Abstract ("A nerve guidance channel for use in regenerating severed nerve is prepared containing a tubular semi-permeable membrane having openings adapted to receive the ends of a severed nerve, and an inner lumen containing the matrix having an adhesive peptide fragment through which the nerve can regenerate."); Fig. 6; col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 4:9-14; col. 4:21-39 ("Any suitable hydrogel may be used as the substrate for the bioartificial extracellular matrices of this invention."); col. 4:48-57; col. 5:10-14 ("Several physical properties of the hydrogel matrices of this invention are dependent on gel concentration. Increase in gel concentration may change the gel pore radius, morphology, or its permeability to different molecular weight proteins."); col. 7:13-25; col. 10:28-40 ("Permselective channels with a molecular weight cut-off of 50,000 daltons allowed regeneration of nerves in a mouse sciatic nerve model."); col. 10:41-63; col. 10:64-11:13; col. 12:13-16 ("Preferably the permselective membrane is fabricated to be impermeable to some of these substances so that they are retained in the proximity of the

regenerating nerve ends."); col. 12:17-25 ("Briefly, various polymers and polymer blends can be used to manufacture the nerve guidance channel."); col. 12:42-49; col. 19:7-16; col. 23:54-24:55.

Dayton '382: Abstract ("The device comprises a stent which is formed from metal or polymers into a predetermined shape which includes a plurality of holes . . . to provide a desired bending modulus. The stent is then coated with a polymer . . . which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids, with the equilibrium being controlled by charge distribution, concentration and molecular weight of the bioactive substance in relation to the pore size of the polymeric carrier for controlled prolonged release of said bioactive substance."); Figs. 4, 7, 9, 10, 12, 14; col. 3:62-4:17 ("Among these polymers are polymers having a microporous structure, such as . . . biodegradable polylactic acid polymers, polyglycolic acid polymers . . ."); col. 4:24-33 ("A bioactive substance is preferably admixed in the polymer for elution from the microporous structure of the stent or coating on the stent after implantation. The rate of elution of the bioactive substance is controlled by selecting a pore size for microporous structure . . ."); col. 4:42-50; col. 4:54-5:3; col. 6:64-7:7 ("The polymer should have a microporous structure with a predetermined pore size."); col. 8:18-33 ("a polymer forming the exterior surface of said stent for operative contact with said tissue . . ."); col. 8:42-59; col. 8:66-9:5; col. 10:1-2.

Burt '036: Fig. 14B; p. 4:19-33 ("Similarly a wide variety of polymeric carriers may be utilized, representative examples of which include poly(ethylene-vinyl acetate) . . . and copolymers of polylactic acid and polycaprolactone."); p. 10:17-25; p. 14:9-27 ("As noted above, anti-angiogenic compositions of the present invention comprise an anti-angiogenic factor and a polymeric carrier. In addition to the wide array of anti-angiogenic factors and other compounds discussed above, anti-angiogenic compositions of the present invention may include a wide variety of polymeric carriers, including for example both biodegradable and non-biodegradable compositions."); p. 21:2-4; p. 21:25-22:6 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size."); p. 51:1-52:35.

Goldin '568: Figs. 1A, 5A-5F; col. 1:43-62 ("Release by controlled diffusion may be accomplished by means of containment of the therapeutic agent within a substrate whose small pore size and/or tortuosity of diffusion path thereof limits the diffusion of said agent through the substrate. . . . The therapeutic agent can be incorporated within the diffusion-limiting substrate . . . Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:24-29 ("Microporous membranes for release of proteins by controlled diffusion have been fabricated from ethylene vinyl acetate (EVA), and said membranes have been used in vivo in a manner which demonstrates their therapeutic potential."); col. 5:28-34 (" . . . underlayment material of controlled pore size can be created and used to fabricate a device of optimal porosity . . . and accessibility of the releasable macromolecule to biological material at or beyond the membrane's external surface . . ."); col. 11:58-12:14; col. 13:53-65; col. 14:1-28; col. 14:66-15:67; col. 31:57-32:7 ("The device of claim 1 wherein said microporous underlayment comprises a polymer."); col. 32:16-22.

Palmaz '665: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); Figures 5 and 6; col. 3:20-25 ("The present invention includes a tubular shaped member having first and second ends and a wall surface disposed between the first and second ends..."); col.3:47-51 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5:30-32 ("FIGS. 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon."); col. 5:58-63; col. 4:24-28.

Palmaz '762: Col. 3:34-37("The present invention includes a tubular shaped member having first and second ends and a wall surface disposed between the first and second ends..."); 3:65-4:2 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 4:43-46; col. 6:9-13; col. 9:20-25; col. 10:28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '337: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col. 3:27-30 ("The present invention includes a tubular shaped member having first and second ends and a wall surface disposed between the first and second ends..."); col.3:52-56 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 4: 29-34; col. 5:19-21; Figures 5 and 6; col. 8:28-32; col. 9:24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials."); col. 5:65-6:2.

Zaffaroni '254: Abstract ("The wall is formed in at least a part of a microporous material..."); col. 1:19-23 ("The wall of the device is comprised in at least a part of a microporous material..."); col. 3:5-10; col. 3:42-45 ("In accomplishing these objects and advantages of this invention, one feature of the invention, in its broadest aspect resides in a novel drug delivery device comprising a wall enclosing a reservoir."); col. 3:48-53; col. 4:41 ("Drug delivery device 10 is comprised of a wall 11..."); col. 4:47-54 ("Wall 11 is formed of a microporous material the micropores 15 of which contain a drug release rate controlling medium, not shown, permeable to the passage of drug, as by diffusion, or by convection, or by a concurrent operation of both, but the rate of passage of the drug through the medium in the micropores is lower than the rate of passage of drug through the solid drug carrier."); col. 5:3-11; col. 6: 27-30.

Engelberg & Kohn: p. 298; p. 299 ("Whilst L-PLA showed a purely elastic deformation for most of the stress-strain curve, D,L-PLA was more ductile and exhibited a significantly larger proportion of plastic deformation."); p. 301 ("Compression moulding [of PCL] yielded opaque,

flexible films.") ("Transparent films [of PTMC] were readily obtained by compression moulding at 40 °C using a low load of 0.5 tonnes. The films could be rolled up and deformed without breaking.").

Aebischer: p. 283 (disclosing preparation of polymer tube made of ethylene-vinyl acetate copolymer); Fig. 2A (disclosing one major surface facing the nerve stumps and another major surface facing away from the nerve stumps).

Dev: p. 273 ("We used a commercially available biomedical grade polyurethane Tecoflex is a biocompatible, flexible, and an elastic membrane-forming polymer.").

Claim 1 [1C] (cont'd): the layer being capable of being shaped in three dimensions by manipulation by human hands,

Where Found in the Prior References:

Peterson '166: Col. 2:51-54 ("Typical polymeric carriers are polyesters, polyamides, polyurethanes and other condensations polymers . . .").

Schwartz '823: Abstract ("A radially expandable stent . . . the cylindrical body comprising a plurality of metal elements joined to allow flexing of the cylindrical body along the longitudinal axis of the body whereby the stent can conform to a curved body lumen . . ."); col. 1:9-14; col. 1:17-19; col. 1:53-55; col. 2:16-19 ("It is therefore an object of the present invention to provide a stent having longitudinal flexibility which allows it to conform to curves and variation in body lumens."); col. 2:29-40; col. 2:44-49; col. 3:48-57; col. 3:58-64 ("The improvement of the present invention includes applying to the above-mentioned type of stent a flexible or elastomeric polymeric film which extends between the metal elements."); col. 4:20-27 ("The term 'film' or 'flexible film' herein therefore means that, as applied to the metal stent elements in a thin cross section, the film is capable of flexing or stretching to preserve the radial expandability and axial flexibility of the implanted stent."); col. 4:49-5:41 ("It also produces a stent having a flexible film which extends between the metal elements of the stent and which will not significantly affect the ability of the stent to conform to curved body lumens. . . . A suitable crimping tool . . . may be used to tighten the stent over the balloon. A manual operation of sequentially squeezing the stent over the balloon is also acceptable."); col. 5:65-6:1; col. 6:17-20; col. 6:30-32; col. 6:43-47; col. 6:49-52; col. 6:58-68; col. 8:19-41.

Scott '928: Col. 8:23-60 (disclosing use of EVA).

Tartaglia '113: Abstract; col. 1:15-19 ("Ideally, implantation of such stent is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:57-60 ("The invention accordingly provides for a drug loaded stent, comprising an

expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member."); col. 1:64-67 ("The polymer material can be a thermoplastic or an elastomer, for example, so that the film can stretch or deform radially when the stent structural member is expanded."); col. 2:23-33; col. 2:48-55; col. 5:6-10; col. 6:54-56; col. 7:18-21 ("The apertures also improve the flexibility of the polymeric material, allowing the stent segment to be more easily rolled and uncoiled during expansion of the stent structural member . . ."); col. 10:40-47.

Wolff '208: Col. 2:7-9 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 9:39-42 ("The device is fixed into place either by radial expansion in devices such as shown in Fig. 1 or are deformed by a balloon catheter in the case of devices in accordance with Fig. 2."); col. 10:3-45 ("The stents are arranged on the distal end of the catheter such that the catheter can provide remote, transluminal deployment of the stents, with the metal stent inside the polymeric stent, from an entry point into a selected portion of the body lumen to be treated and also remote actuation of an expansion mechanism from the proximal end of the catheter. The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen."); col. 10:51-57; col. 10:66-11:3 ("The metal stent is crimped onto the balloon and includes an elongated lead extending to the proximal end of the catheter assembly where it includes an enlarged portion to enable an operator to securely grip the lead."); col. 12:1-15.

Berg '354: Page 2:14-15 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen."); p.3:18-22 ("The transluminal delivery can be accomplished by a catheter designed for the delivery of stents and the radial expansion can be accomplished by balloon expansion of the stent, by self-expansion of the stent, or a combination of self-expansion and balloon expansion. Thus the present invention provides a stent which may be delivered and expanded in a selected blood vessel without losing a therapeutically significant amount of a drug applied thereto."); p. 5:28-29.

Buscemi '450: Col. 1:58-60; col. 7:10-20 (" . . . said tubular main body including a slot extending lengthwise through the main body and defined by opposing edges of the main body wherein the opposing edges must be moved toward each other under compression in order to transport the biodegradable stent through a vessel of a living being . . ."); col. 8:18-24.

Ding '536: Col. 1:48-51 ("One type of self-expanding stent has a flexible tubular body formed of several individual flexible thread elements each of which extends in a helix configuration with the centerline of the body serving as a common axis."); col. 3:5-9; col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 3:56-64 (" . . . the tubular body is formed of a self-expanding open braid

of fine, single or polyfilament metal wire which flexes without collapsing, readily axially deforms to an elongate shape for transluminal insertion via a vascular catheter and resiliently expands toward predetermined stable dimensions upon removal in situ.").

Dinh '227: Col. 1:32-35 ("The stent is typically inserted by catheter into a vascular lumen told [sic] expanded into contact with the diseased portion of the arterial wall, thereby providing mechanical support for the lumen."); col. 2:62-66 ("The inclusion of a polymer in intimate contact with a drug on the underlying stent structure allows the drug to be retained on the stent in a resilient matrix during expansion of the stent and also slows the administration of drug following implantation."); col. 3:14-22; col. 6:62-67; col. 7:13-21; col. 8:29-43 ("For example, a deformable metal wire stent such as that disclosed in U.S. Pat. No. 4,886,062 issued to Wiktor could be coated with fibrin as set forth above The stent and fibrin would could then be placed onto the balloon at a distal end of a balloon catheter and delivered by conventional percutaneous means . . . to the site of the restriction or closure to be treated where it would then be expanded into contact with the body lumen by inflating the balloon."); col. 8:49-52 ("A catheter has a balloon upon which a stent has been placed, the stent having a deformable metal portion and a fibrin coating, thereon."); col. 8:64-9:2; col. 9:18-24; col. 9:49-50 ("The resulting fibrin stent includes the stent embedded in a very thin elastic film of fibrin."); col. 9:59-63; col. 12:24-28.

Domb '055: Abstract ("Preferred embodiments include catheters, tubes, and implants that abut tissue following implantation into the body . . ."); col. 4:25-32; col. 5:27-37 ("In a particularly preferred embodiment, polymers incorporating steroids are coated onto devices including tracheal T-tubes, stoma stents, laryngeal/bronchial stents, laryngeal keels, and nasogastric tubes."); col. 5:46-54; col. 5:60-62; col. 7:10-20; col. 7:40-52; col. 9:15-30; col. 9:55-10:2; col. 10:21-52; col. 10:60-11:11.

Fox '096: Col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages.").

Hunter '981: Col. 16:31-56; col. 17:63-18:7 ("[T]he anti-angiogenic compositions of the present invention may be formed as a film. . . . Such films are preferably flexible with a good tensile strength . . . and has controlled permeability."); col. 22:3-7; col. 22:21-39; col. 22:54-58; col. 23:26-30; col. 60:35-45; Fig. 17E; col. 66:13-22 ("As discussed above, sterile, pliable, stretchable drug-polymer compounds (e.g., films) may be utilized in accordance with the methods described herein in order to isolate normal surrounding tissues from malignant tissue during resection of cancer.").

Kowligi '782: Col. 4:28-37.

Lambert '922: Col. 3:54-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand

certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); col. 8:1-6.

Lambert '308: Page 6:21-28 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected.").

Myler '563: Abstract ("When elongated in an axial direction, the stent is reduced in cross-sectional area."); col. 2:13-16 ("The stent is configured to permit radial expansion, such as under the force generated by balloon dilation, and radial contraction in response to axial elongation."); col. 2:22-26; col. 2:27-28; col. 3:13-15; col. 3:33-34; col. 3:44-46; col. 3:48-51 ("Alternatively, tubular stents formed from flexible non-metal materials such as elastomeric polymers or rubber (latex) can also be radially reduced by axial elongation in accordance with the present invention."); col. 3:58-61; col. 4:9-12; col. 4:30-43 ("Suitable envelope materials include elastic materials such as latex and others that can be readily selected by one of skill in the art. . . . In general, biocompatible materials which can tolerate expansion of the stent between the insertion diameter and expanded diameter can be used."); col. 5:1-16; col. 5:50-54; col. 6:18-23; col. 10:12-14 ("The balloon is inflated, thereby expanding the stent radially outwardly until it contacts either a previously dilated, or presently stenosed wall."); col. 11:55-58; col. 11:63-65; col. 12:11-13; col. 12:19-23; col. 12:63-13:1 ("Suitable coating materials include elastic materials such as polyethylene or PET or other materials that can be readily selected by one of skill in the art. In general, any biocompatible material which can tolerate expansion of the stent between the insertion diameter and treatment diameter can be used."); col. 13:61-66; col. 19:18-30; col. 19:65-20:7; col. 20:51-57.

Palmaz '417: Col. 11:11-14 ("The coating should be thin and highly elastic so as not to interfere with the desired expansion and deformation of prosthesis, or graft."); col. 13:22-24; col. 13:30-40.

Aebischer '486: Col. 3:56-63.

Schiraldi '243: Col. 1:8-21 ("The extruded film drug delivery system of the present invention, which has incorporated therein the medicament to be dispensed, is so thin and flexible when wet as to be unobtrusive to the patient after it has been properly positioned and placed in the mouth."); col. 2:30-51.

Valentini '029: Col. 1:56-2:4; col. 2:29-41 ("The devices can be formed from various polymeric materials, such as acrylic copolymers, polyvinylidene fluoride or polyurethane isocyanate, adapted to receive the ends of the severed or otherwise damaged nerve."); col. 3:62-67 ("The sheet is then wrapped around the nerve segments and the resulting tube is closed by further sutures, adhesives or friction."); col. 4:46-59 (disclosing use of flexible polymeric materials).

Wood '066: Abstract; col. 2:56-3:17; col. 7:51-65; col. 17:19-22; col. 17:30-34 ("... to give a flexible, elastomeric, white cryogel membrane ..."); col. 18:1-4; col. 18:13-16; col. 18:26-30.

Strecker '746: Abstract ("An endoprosthesis in the form of an elongated hollow structure ... once correctly positioned will expand from an initial state with a narrow lumen into a state with a lumen that is as wide as its placement will allow. It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen."); col. 1:12-22 ("Once correctly positioned it will expand from an initial state with a narrow lumen into a state with a lumen that is as wide as its placement will allow. ... The lumens can be expanded by mechanically stretching them with a known balloon catheter. They can also be compressed prior to implantation and stretch out on their own subject to the resilience introduced by the compression."); col. 1:63-2:2; col. 2:21-32; col. 2:33-38; col. 2:65-3:4; col. 6:30-32; col. 7:16-35; col. 8:19-10:19.

Lambert '246: Col. 3:55-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected.)").

Bellamkonda '029: Col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 4:48-57; col. 10:32-40; col. 11:33-40.

Dayton '382: Abstract ("The device comprises a stent which is formed from metal or polymers into a predetermined shape which includes a plurality of holes ... to provide a desired bending modulus."); col. 3:62-4:12; col. 4:42-50; col. 4:54-5:3; col. 8:42-59.

Burt '036: p.14:9-27; p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size.").

Goldin '568: Col. 1:55-62 ("Materials that have been used to fabricate diffusion-controlled slow release devices ... include ethylene-vinyl acetate copolymers ... and hydroxylalkyl methacrylates."); col. 2:8-12; col. 2:24-29 ("Microporous membranes for release of proteins by controlled diffusion have been fabricated from ethylene vinyl acetate (EVA) ...").

Palmaz '762: Col. 10: 28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '337: Col. 9: 24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Aebischer: p. 284 (disclosing manipulation of polymer tube to allow entry of nerve stumps).

Dev: p. 273 ("We used a commercially available biomedical grade polyurethane Tecoflex is a biocompatible, flexible, and an elastic membrane-forming polymer.").

Claim 1 [1D] (cont'd): the first major surface of the layer being adapted to be placed adjacent to a damaged tissue,

Where Found in the Prior References:

Schwartz '823: Abstract ("The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen."); Figs. 6-9, 13, 15; col. 2:37-40 ("In essence, this improvement makes it possible to provide a stent able to support body lumens and conform to curves or irregularities in body lumens."); col. 2:44-54 ("The composite stent of the present invention can be delivered to the site of the occlusion by catheter and expanded conventionally, causing the film to expand or open radially along with the metallic elements of the stent and to be brought into contact with the body lumen. The polymeric film is flexible and preferably an elastic or stretchable film that is capable of conforming to the movement of the metallic stent elements when expanded into contact with a body lumen."); col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:48-54; col. 3:58-col. 4:6; col. 6:49-52 ("As shown in Fig. 13, the stent can be delivered to the body lumen and expanded (e.g. by use of a balloon catheter) into contact with the body lumen."); col. 6:33-37 ("As shown in Fig. 9, with the angioplasty procedure completed, balloon is deflated and withdrawn leaving stent firmly implanted within vessel with the film held in contact with the vessel."); col. 6:62-68 ("Once in the desired location, the stent can be released from the catheter and expanded into contact with the lumen as shown in Fig. 15 where it can conform to the curvature of the body lumen. The flexible film is able to form folds which allow the stent elements to readily adapt to the curvature of the body lumen.").

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer

sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14 ("The present invention satisfies this need by providing a separate sleeve to encompass the stent and serve as a local drug delivery device to prevent thrombosis."); col. 4:53-55 ("The present invention satisfies this need by providing a separate sleeve to encompass a stent to locally administer drugs to prevent restenosis."); col. 4:58-68 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. . . . Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 5:26-29; col. 6:49-55 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface); col. 8:8-22; col. 8:58-60 ("The films were placed to line the circumference of a 2 cm length of ePTFE grafts, over which a 2 cm long stent was deployed."); col. 9:12-16 ("In addition, polymer-drug films which prevent thrombosis in the baboon and pig AV shunt system can be studied following stent-film placement in carotid, superficial femoral and coronary arteries following balloon injury of those vessels."); col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Fig. 8; col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:12-20 ("Stents are typically implanted within a vessel in a contracted state and expanded when in place in the vessel in order to maintain patency of the vessel to allow fluid flow through the vessel. Ideally, the implantation of such stents is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:25-38 ("Since it is often useful to provide

localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:50-56 ("The stent can be used in coronary arteries or any other part of the vasculature or other body lumen where mechanical opening force is necessary or desirable to keep the vessel open or to maintain the stent flush against the lumen wall, and where an anti-restenosis, anti-proliferative or other types of therapeutic drug or agent is to be simultaneously positioned and diffused."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 2:23-33; col. 5:15-17; col. 7:56-62; col. 9:63-67 ("The deployment of the stent can also be improved by . . . decreasing friction between the vessel or lumen wall and the stent."); col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:52-54 ("The invention provides prostheses which may be inserted into a lumen of a body and fixed to the lumen wall adjacent an area needing treatment."); col. 1:63-66 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery."); col. 2:7-9 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:25-27 ("The current invention contemplates the usage of any prosthesis which elutes drugs locally to treat a lumen in need of repair."); col. 6:36-38; col. 6:56-58 ("The stent shown in Figs. 2 and 4 is a metallic malleable design which may be forced against a lumen wall by a balloon catheter which fixes it into position."); col. 6:64-67 ("The variations of design shown in the embodiments of Figs. 1 and 2 show that the prosthesis of the invention must be secured against a lumen wall and must carry a drug-eluting polymer."); col. 9:67-10:3 ("By including a metal stent within the lumen of the polymeric prosthesis, the polymeric prosthesis is effectively held against the wall of the body lumen by the strength of the metal stent."); col. 10:23-38 ("The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen. This will bring the bioabsorbable element into supporting contact with a body lumen at an interior position of the body lumen to be treated and will position the bioabsorbable element to deliver drugs to the body lumen. Following the expansion of the stents into luminal contact, the balloon (if the expansion device is a balloon) can be deflated which allows the luminal flow to be restored."); col. 10:46-59; col. 11:10-13; col. 11:17-20; col. 11:50-53 ((b) a body including a plurality of support elements forming an open-ended, radially expandable, self-supporting tubular structuring having an interior surface and an exterior surface."); col. 12:1-15.

Berg '354: Page 2:14-18 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen. Examples of stents which have been successfully applied over a PTCA balloon and radially expanded at the same time as the balloon expansion of an affected artery include the stents disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) which are incorporated herein by reference in their entirety."); p. 2:34-36 ("Metal stents such as those disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) could be suitable for drug delivery in that they are capable of maintaining intimate contact between a substance applied to the outer surface of the stent and the tissues of the vessel to be treated."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:16-18 ("In operation, the stent made according to the present invention can deliver drugs to a body lumen by introducing the stent transluminally into a selected portion of the body lumen and radially expanding the stent into contact with the body lumen.").

Buscemi '450: Col. 3:14-15 ("The stent strengthens an area of the vessel that is in contact with the stent."); col. 3:21-25 ("The tubular main body includes an outer surface and inner surface. The outer surface of the main body faces an inner surface wall of the vessel. The inner surface of the stent faces a stream flowing through the lumen as shown in cross section in Fig. 2."); col. 4:61-64 ("The stent is secured by releasing the stent from compression so that the stent can radially spring out to abut against the inner surface wall of the vessel."); col. 6:49-52; col. 7:27-29; col. 8:9-11.

Ding '536: Col. 5:38-40 ("Surface material should minimize tissue rejection and tissue inflammation and permit encapsulation by tissue adjacent the stent implantation site.").

Dinh '227: Col. 1:32-35 ("The stent is typically inserted by catheter into a vascular lumen told [sic] expanded into contact with the diseased portion of the arterial wall, thereby providing mechanical support for the lumen."); col. 8:20-23 ("The term "stent" herein means any device which when placed into contact with a site in the wall of a lumen to be treated, will also place fibrin at the lumen wall and retain it at the lumen wall."); col. 8:37-43; col. 9:18-24 ("The stent is then delivered through the body lumen on the catheter to the treatment site where the stent is released from the catheter to allow it to expand into contact with the lumen wall.").

Domb '055: Abstract ("Preferred embodiments include catheters, tubes, and implants that abut tissue following implantation into the body . . ."); col. 4:25-32; col. 5:27-33; col. 5:49-54; col. 5:63-6:1 ("Coating that part of the tube, which is in contact with the mucosa, with the drug-loaded polymer provides a sustained release of steroids and antibiotics locally and at high concentration in the area which is critically affected, achieving the same effect as the systemic administration of the drugs without their side effects, throughout the duration of the intubation."); col. 6:8-18; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior

surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages.").

Kowligi '782: Abstract; col. 1:18-41; Figs. 2, 3; col. 10:18-67.

Hunter '981: Col. 4:24-38; col. 5:1-6; col. 16:31-56; col. 22:3-7; col. 22:54-58; col. 23:6-13 ("[M]ethods are provided for expanding the lumen of a body passageway, comprising inserting a stent into the passageway, the stent having a generally tubular structure, the surface of the structure being coated with an anti-angiogenic composition . . . such that the passageway is expanded."); col. 23:30-31; col. 23:46-51; col. 24:45-51; col. 24:66-25:5; col. 25:24-29; col. 25:48-54; col. 52:4-8 ("This film is designed to be placed on exposed tissue so that any encapsulated drug is released from the polymer over a long period of time at the tissue site."); 86:56-59; col. 87:11-22; col. 88:19-26.

Lambert '922: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion."); col. 3:54-61; col. 8:1-6.

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Myler '563: Col. 3:34-37 ("Stent 10 is illustrated in its expanded position at a treatment location adjacent vascular wall in an artery, in accordance with one aspect of the present invention."); col. 4:53-56 ("The exterior surface of the envelope which will contact the arterial wall is optionally made porous to enable the release of drugs from the envelope and/or stent to the treatment site."); col. 10:12-14 ("The balloon is inflated, thereby expanding the stent radially outwardly until it contacts either a previously dilated, or presently stenosed wall."); col. 10:56-61; col. 11:63-65 ("Once the stent has been positioned at the treatment site, axial elongating tension is released, and it is permitted to radially expand against the lumen wall."); col. 13:15-17 ("The exterior coating which will contact the arterial wall is optionally made porous to enable the release of drugs to the treatment site.").

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active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); Figs. 1 and 2; col. 9:18-10:3.

Schiraldi '243: Col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Valentini '029: Abstract ("In particular, tubular channels which have a smooth inner surface and longitudinally oriented trabeculae result in significantly larger regenerated nerve cables and higher numbers of regenerated myelinated axons."); Figure 3; col. 2:32-35 ("Medical devices employing such selectively permeable materials, particularly semipermeable tubular devices having smooth inner skins, are disclosed for use in regenerating nerves."); col. 2:58-3:14; col. 5:33-41; col. 6:14-24.

Bawa '279: Col. 6:40-44; col. 12:29-34.

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Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:63-2:2; col. 2:21-32; col. 2:33-38; col. 2:39-46; col. 3:63-4:31 ("It can be of advantage for the lining to be of several layers, each impregnated with different medications. . . . It has also been demonstrated practical for the inner layer of the lining to be impregnated with antithrombotics and the outer with antiproliferatives and/or other medicational substances."); Fig. 4; col. 5:18-20 ("Fig. 4 is a view similar to that of Fig. 2 of an endoprosthesis with a multiple-layer lining and with its ends coated with medication,"); col. 5:34-41 ("The endoprosthesis . . . is completely enclosed in an inner lining component and an outer lining component."); Fig. 7; Fig. 8; col. 6:30-44 ("The endoprosthesis 40 in the embodiment illustrated in Fig. 7 comprises a lining 42 and 43 in the form of a double walled sleeve. The outer lining component 43 of the in-place and expanded stent rests against the inner surface 46 of the blood vessel. Inner lining component 42 rests against the stent."); col. 7:16-35; col. 7:48-65; col. 8:19-10:19.

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Bellamkonda '029: Fig. 6.

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Burt '036: p.14:9-27; p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size.").

Goldin '568: Figs. 5A-5F; col. 9:7-12 (" . . . a substance that, when implanted in or juxtaposed against a living body . . ."); col. 22:46-23:3.

Palmaz '665: Col.3: 55-65 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into the body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded..."); col. 5:9-13; Figure 4; col. 8:9-14.

Palmaz '762: Col. 4: 14-19 (...expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway..."); col. 4: 53-56; col. 5: 43-45; col. 9: 1-6.

Palmaz '337: Col. 3:60-4:2 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into a body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded, whereby the intraluminal graft prevents the body passageway from collapsing and decreasing the size of the expanded lumen."); col. 4: 36-40; col. 5: 32-34; col. 7: 28-36; col. 8: 17-22.

Zaffaroni '254: Col. 7: 18-25 ("Secondly, the carrier contacts and bathes the inner surface of wall 11 for facilitating drug transfer from the carrier to the wall so that drug molecules can dissolve in a diffusive medium in the microporous wall and migrate through it to the outer surface thereof.").

Aebischer: Fig. 2A (disclosing one major surface facing the nerve stumps).

Dev: Abstract ("Polymer-coated stents could be used for local drug delivery to the vessel wall."); p. 273 ("... to compare these two drugs with respect to kinetics of their delivery to the arterial wall with the stent in place ...").

Claim 1 [1E] (cont'd): the second major surface of the layer being adapted to be placed opposite to the damaged tissue,

Where Found in the Prior References:

Schwartz '823: Abstract ("The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen."); Figs. 6-9, 13, 15; col. 2:37-40 ("In essence, this improvement makes it possible to provide a stent able to support body lumens and conform to curves or irregularities in body lumens."); col. 2:44-54 ("The composite stent of the present invention can be delivered to the site of the occlusion by catheter and expanded conventionally, causing the film to expand or open radially along with the metallic elements of the stent and to be brought into contact with the body lumen. The polymeric film is flexible and preferably an elastic or stretchable film that is capable of conforming to the movement of the metallic stent elements when expanded into contact with a body lumen."); col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:48-54; col. 3:58-col. 4:6; col. 6:49-52 ("As shown in Fig. 13, the stent can be delivered to the body lumen and expanded (e.g. by use of a balloon catheter) into contact with the body lumen."); col. 6:33-37 ("As shown in Fig. 9, with the angioplasty procedure completed, balloon is deflated and withdrawn leaving stent firmly implanted within vessel with the film held in contact with the vessel."); col. 6:62-68 ("Once in the desired location, the stent can be released from the catheter and expanded into contact with the lumen as shown in Fig. 15 where it can conform to the curvature of the body lumen. The flexible film is able to form folds which allow the stent elements to readily adapt to the curvature of the body lumen.").

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14 ("The present invention satisfies this need by providing a separate sleeve to encompass the stent and serve as a local drug delivery device to prevent thrombosis."); col. 4:53-55 ("The present invention satisfies this need by providing a

separate sleeve to encompass a stent to locally administer drugs to prevent restenosis."); col. 4:58-68 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. . . . Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 5:26-29; col. 6:49-55 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface); col. 8:8-22; col. 8:58-60 ("The films were placed to line the circumference of a 2 cm length of ePTFE grafts, over which a 2 cm long stent was deployed."); col. 9:12-16 ("In addition, polymer-drug films which prevent thrombosis in the baboon and pig AV shunt system can be studied following stent-film placement in carotid, superficial femoral and coronary arteries following balloon injury of those vessels."); col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:12-20 ("Stents are typically implanted within a vessel in a contracted state and expanded when in place in the vessel in order to maintain patency of the vessel to allow fluid flow through the vessel. Ideally, the implantation of such stents is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:50-56 ("The stent can be used in coronary arteries or any other part of the vasculature or other body

lumen where mechanical opening force is necessary or desirable to keep the vessel open or to maintain the stent flush against the lumen wall, and where an anti-restenosis, anti-proliferative or other types of therapeutic drug or agent is to be simultaneously positioned and diffused."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 2:23-33; col. 5:15-17; col. 7:56-62; col. 9:63-67 ("The deployment of the stent can also be improved by . . . decreasing friction between the vessel or lumen wall and the stent."); col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:52-54 ("The invention provides prostheses which may be inserted into a lumen of a body and fixed to the lumen wall adjacent an area needing treatment."); col. 1:63-66 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery."); col. 2:7-9 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:25-27 ("The current invention contemplates the usage of any prosthesis which elutes drugs locally to treat a lumen in need of repair."); col. 6:36-38; col. 6:56-58 ("The stent shown in Figs. 2 and 4 is a metallic malleable design which may be forced against a lumen wall by a balloon catheter which fixes it into position."); col. 6:64-67 ("The variations of design shown in the embodiments of Figs. 1 and 2 show that the prosthesis of the invention must be secured against a lumen wall and must carry a drug-eluting polymer."); col. 9:67-10:3 ("By including a metal stent within the lumen of the polymeric prosthesis, the polymeric prosthesis is effectively held against the wall of the body lumen by the strength of the metal stent."); col. 10:23-38 ("The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen. This will bring the bioabsorbable element into supporting contact with a body lumen at an interior position of the body lumen to be treated and will position the bioabsorbable element to deliver drugs to the body lumen. Following the expansion of the stents into luminal contact, the balloon (if the expansion device is a balloon) can be deflated which allows the luminal flow to be restored."); col. 10:46-59; col. 11:10-13; col. 11:17-20; col. 11:50-53 ((b) a body including a plurality of support elements forming an open-ended, radially expandable, self-supporting tubular structuring having an interior surface and an exterior surface."); col. 12:1-15 ("(c) at least one flexible, polymeric filament attached to the support elements of the body, at least a portion of the filament exposed at the exterior surface of the tubular body, said body mounted on the catheter at the distal end thereof;").

Berg '354: Page 2:14-18 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing

internal support for the lumen. Examples of stents which have been successfully applied over a PTCA balloon and radially expanded at the same time as the balloon expansion of an affected artery include the stents disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) which are incorporated herein by reference in their entirety."); p. 2:34-36 ("Metal stents such as those disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) could be suitable for drug delivery in that they are capable of maintaining intimate contact between a substance applied to the outer surface of the stent and the tissues of the vessel to be treated."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:16-18 ("In operation, the stent made according to the present invention can deliver drugs to a body lumen by introducing the stent transluminally into a selected portion of the body lumen and radially expanding the stent into contact with the body lumen.").

Buscemi '450: Col. 3:14-15 ("The stent strengthens an area of the vessel that is in contact with the stent."); col. 3:21-25 ("The tubular main body includes an outer surface and inner surface. The outer surface of the main body faces an inner surface wall of the vessel. The inner surface of the stent faces a stream flowing through the lumen as shown in cross section in Fig. 2.") col. 4:61-64 ("The stent is secured by releasing the stent from compression so that the stent can radially spring out to abut against the inner surface wall of the vessel."); col. 6:49-52; col. 7:27-29; col. 8:9-11.

Ding '536: Col. 5:38-40 ("Surface material should minimize tissue rejection and tissue inflammation and permit encapsulation by tissue adjacent the stent implantation site.").

Dinh '227: Col. 1:32-35 ("The stent is typically inserted by catheter into a vascular lumen told [sic] expanded into contact with the diseased portion of the arterial wall, thereby providing mechanical support for the lumen."); col. 8:20-23 ("The term "stent" herein means any device which when placed into contact with a site in the wall of a lumen to be treated, will also place fibrin at the lumen wall and retain it at the lumen wall."); col. 8:37-43; col. 9:18-24 ("The stent is then delivered through the body lumen on the catheter to the treatment site where the stent is released from the catheter to allow it to expand into contact with the lumen wall.").

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of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

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Strecker '746: Figs. 7 & 8.

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Burt '036: p.14:9-27; p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size.").

Goldin '568: Figs. 5A-5F; col. 9:7-12 (" . . . a substance that, when implanted in or juxtaposed against a living body . . ."); col. 22:46-23:3.

Palmaz '665: Col. 3:55-65 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into the body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded..."); col. 5:9-13; Figure 4; col. 8:9-14.

Palmaz '762: Col. 4: 14-19 (...expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway..."); col. 4: 53-56; col. 5: 43-45; col. 9: 1-6.

Palmaz '337: Col. 3:60-4:2 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into a body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded, whereby the intraluminal graft prevents the body passageway from collapsing and decreasing the size of the expanded lumen."); col. 4: 36-40; col. 5: 32-34; col. 7: 28-36; col. 8: 17-22.

Zaffaroni '254: Col. 7: 18-25 ("Secondly, the carrier contacts and bathes the inner surface of wall 11 for facilitating drug transfer from the carrier to the wall so that drug molecules can dissolve in a diffusive medium in the microporous wall and migrate through it to the outer surface thereof.").

Aebischer: Fig. 2A (disclosing one major surface facing away from the nerve stumps).

Dev: Abstract ("Polymer-coated stents could be used for local drug delivery to the vessel wall."); p. 273 (" . . . to compare these two drugs with respect to kinetics of their delivery to the arterial wall with the stent in place . . .").

Claim 1 [1F] (cont'd): the layer having material release means for release of an at least one treating material in a directional manner when said layer is placed adjacent to a damaged tissue

Where Found in the Prior References:

Peterson '166: Abstract ("A time-release chemical delivery system in which a bioactive compound is attached to a polymeric biodegradable carrier by a hydrolysable bond is disclosed. The bioactive compound can either be bound directly to the polymer or be attached to the polymer via a spacer group."); col. 1:28-38; col. 1:51-55 ("Another object of the instant invention is to provide a bioactive compound via covalent bonding to a polymeric backbone so that upon hydrolysis of said covalent bond said bioactive compound is released in active, unmodified form."); col. 1:60-62; col. 1:67-col. 2:2; col. 2:40-50 ("A further requirement of the polymeric carriers are that they contain a pendant group to which a reactive compound may be directly attached by a hydrolyzable bond or to which a spacer unit may be attached with the reactive compound attached to the spacer unit by a hydrolysable bond. Typically, the space [sic] unit will also be attached to the polymeric carrier by a hydrolyzable bond."); col. 2:51-60; col. 3:67-4:2; col. 4:3-7 ("The use of a spacer group may also provide desirable changes in drug release rate by allowing ease of hydrolysis of the drug."); col. 4:8-19; col. 4:56-5:2; col. 6:28-55; col. 6:55-62 ("Since the proximity of the reactive carboxyl group to the polymer backbone may interfere with the addition of a bioactive compound, especially a large molecule, and with the subsequent hydrolysis of a covalent bond formed by such condensation reaction, the use of a spacer group, preferably linear in nature, may be preferred in this invention."); col. 6:65-col.7:28 ("To be effective as hydrolysable carriers the polymers of this invention must have pendant reactive sites to which a bioactive compound may be attached. . . . These functional groups may react with functional groups of the bioactive compound to form a hydrolysable bond. The hydrolysable bond may be direct between the pendant group of the polymer and the reactive compound or it may be first reacted with a spacer unit which contains a similar reactive functional group. . . . The reactivity of the reactive sites is also affected by the distance of the reactive site from the backbone of the polymer."); col. 7:32-53 ("Spacer groups may be utilized in the practice of the instant invention to provide a hydrolysable unit which spaces the reactive compound further from the carrier backbone. As indicated hereinabove, the polymeric units may contain long pendant chains which place the reactive site on the pendant group further away from the carrier backbone. . . ."); col. 7:57-62 ("Bioactive compounds useful in this invention are those which contain a group which may react to form a bond with a pendant group or a spacer group. The bond is preferably hydrolysable and in particular are esters, including sulfates or phosphate esters, amides, carbonates and urethane bonds."); col.8:25-28 ("The reactive compound which is released over a period of time in the instant invention may be one which has a pharmacological affect upon the host, for example, a contraceptive drug in an animal."); col. 8:34-49 ("Factors which affect the release rate and the rate of absorption into the body of the host

include . . . the composition of the polymer backbone, the length and character of the spacer groups and the character of the pendant groups The spacing of the bulky drug or chemically reacted compound from the polymer also affects the rate of release."); col. 11:25-12:4 (" . . . a bioactive compound chemically attached to said carrier by a hydrolysable bond, said bioactive compound containing a group which reacts with a group on the biodegradable polymer to form a hydrolysable bond and being effective in small dosages to produce a biological effect within said host upon release into the host by hydrolysis of the hydrolyzable bond."); col. 12:14-24 ("The chemical delivery system of claim 1 wherein said bioactive compound is indirectly coupled to said carrier by a hydrolyzable bond to a spacer compound. . . . The chemical delivery system of claim 7 wherein said spacer compound is coupled to said bioactive compound by a hydrolyzable bond."); col. 12:28-30.

Schwartz '823: Col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:64-4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof."); col. 7:1-4 ("In yet another aspect of the present invention, various therapeutic substances can be incorporated in or applied to the polymeric film to provide such substances to the blood or to the lumen wall."); col. 7:14-25 ("Application of the therapeutic substance to the film can include applying it on the surface of the film or incorporating it into the film as it is made. For example, microcapsules can be used to carry the therapeutic substance either in or on the film and to provide timed-release of the substance to the blood, or to the blood vessel or both."); col. 7:25-34 ("Microcapsules containing one type of therapeutic substance could be provided on one side of the film and microcapsules containing another therapeutic substance could be incorporated on the other side of the film, thus providing a stent according to the present invention which provides one type of therapeutic substance (e.g. an anti-thrombotic drug) to the blood and another type of therapeutic substance (e.g. an antiproliferative drug) to the vessel wall."); col. 8:5-11 ("The resulting stent has microcapsules containing one therapeutic substance on the inside (and able to contact blood once implanted in a blood vessel) and microcapsules containing a second therapeutic substance on the outside (and able to contact the vessel wall when implanted in contact with the vessel wall)."); col. 8:46-47.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14; col. 4:53-55; col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an

arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-33; col. 5:34-6:23 ("Many polymers can also be used to make the sheath, including biodegradable and non-degradable polymers. The polymer is selected depending on the drug selected, the polymer's compatibility with a subject and the ultimate pharmacologic effect desired. . . . Another alternative would be to use a polymer which is biodegradable over a short period of time. Naturally, the opposite characteristics would be selected for a desired prolonged release. The characteristics of the particular polymer for these purposes is well known to the skilled artisans or can be determined by reference to standard references . . ."); col. 6:39-41 ("The initial prototype is a sleeve of polymer, either degradable or non-degradable, that covers the entire stent (Fig. 3)"); col. 6:64-68 ("The duration of drug delivery is accurately predicted by the characteristics of the polymer. For example, if the polymer is biodegradable, then the rate and duration of drug delivery is related to the thickness of the polymer."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface."); col. 8:23-54; col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33 ("In combination, a hollow tubular stent having a predetermined length and a separate sheath removably encompassing at least a portion of said hollow tubular stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug."); col. 11:11-12 ("14. The sheath of claim 1, wherein the polymer is biodegradable."); col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped

with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 5:4-9 ("The primary function of the sheet of polymeric material is to deliver therapeutic agents or drugs to help prevent thrombosis and/or restenosis."); col. 5:49-6:25 ("The polymeric material is preferably bioabsorbable, and is preferably loaded or coated with a therapeutic agent or drug . . ."); col. 7:23-25; col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:63-2:6 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery. The prostheses may be completely biodegradable or may be bioabsorbable in whole or incorporated into the lumen wall as a result of tissue overgrowth, i.e. endothelialization. Alternatively, the prostheses may be biostable in which case the drug is diffused out from the biostable materials in which it is incorporated."); col. 2:28-30 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 2:55-58; Fig. 5; col. 6:5-10 ("When drugs are delivered locally via the prosthesis of the invention, they may be at therapeutic levels at the diseased site while at the lower limits of detectability in the bloodstream. So little drug is required for effective local treatment of a lumen that the drug may not be detectable in blood samples."); col. 6:36-38; col. 6:59-63 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously. the polymer may be biostable or bioabsorbable. If biostable, the drug would diffuse out of the polymer."); col. 6:64-67; col. 7:19-23; col. 7:53-55 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 7:59-8:25; col. 8:26-31 ("The compound which is preferred is a polyphosphate ester. Polyphosphate ester is a compound such as that disclosed in U.S. Pat. Nos. 5,176,907; 5,194,581; and 5,656,765 issued to Leong which are incorporated herein by reference. Similar to polyanhydrides, polyphosphate ester is being researched for the sole purpose of drug delivery."); col. 8:40-9:22 ("It is the hydrolytic instability of the phosphorous ester bond which makes this polymer attractive for controlled drug release applications. A wide range of controllable degradation rates can be obtained by adjusting the hydrophobicities of the backbones of the backbones of the polymers and yet assure biodegradability. The functional side groups allow for the chemical linkage of drug molecules to the polymer."); col. 12:12-15.

Berg '354: Page 2:27-31 ("Other methods of providing therapeutic substances to the vascular wall include simple heparin-coated metallic stents, whereby a heparin coating is ionically or covalently bonded to the stent. Still other methods of providing therapeutic

substances to the vascular wall by means of stents have also been proposed such as in US-A-5102417 (Palmaz), WO-91/12779 "Intraluminal Drug Eluting Prosthesis" and WO-90/133332 "Stent With Sustained Drug Delivery".); p. 3:7-9; p. 3:22-23 ("It also provides a drug-containing stent which allows for a sustained release of the drug to vascular tissue."); p. 4:25-27 ("The ratio of therapeutic substance to polymer in the solution will depend on the efficacy of the polymer in securing the therapeutic substance onto the stent and the rate at which the coating is to release the therapeutic substance to the tissue of the blood vessel."); p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Abstract ("A stent made of biodegradable material includes a drug that is released at a rate controlled by the rate of degradation of the biodegradable material."); col. 1:61-63; col. 2:6-8 ("The mechanism of biodegradation is described as hydrolysis resulting in degradable products excreted in urine or reabsorbed into tissues."); col. 2:49-52 ("Also desired are stents which can deliver drugs or biologically active agents at a controlled rate to blood passing through the vessel lumen as well as to the vessel wall."); col. 2:56-61 ("The biodegradable stent is made from at least one biodegradable material that is also biocompatible and includes a drug which is released into the lumen of the vessel at a rate controlled by the rate of degradation of the biodegradable material."); col. 3:11-12 ("The rate of drug release is controlled by the rate of degradation of the biodegradable materials."); col. 3:53-55; col. 4:12-14; col. 4:23-25 ("The present invention further includes a main body having more than one biodegradable interior film layer."); col. 4:65-5:5 "In the most preferred embodiment, the biodegradable stent of the present invention is made of biodegradable materials that are also biocompatible. By biodegradable is meant that a material will undergo breakdown or decomposition into harmless compounds as part of a normal biological process"); col. 5:11-19 ("Suitable biodegradable materials for the main body of the stent of the present invention include polylactic acid, polyglycolic acid (PGA), collagen or other connective proteins or natural materials, polycaprolactone, hyaluric acid, adhesive proteins, co-polymers of these materials as well as composites and combinations thereof and combinations of other biodegradable polymers."); col. 5:21-37; col. 5:38-45 ("Consequently, the presence of different biodegradable materials in the stent permits the stent to degrade in a predictable, orchestrated fashion."); col. 5:46-54 ("As the stent biodegrades, drugs are administered to the surrounding tissue or to the blood stream. Thus, the rate of drug release is controlled by the rate of degradation of the biodegradable materials."); col. 6:3-8; col. 6:45-59; col. 7:2-9; col. 7:32-8:9; col. 8:27-30.

Ding '536: Abstract ("In one embodiment, the surface is provided with sites of high electronegativity species by coating with fluorosilicone which aid in controlled elution, particularly the initial release rate, and reduce thrombogenic activity."); col. 2:38-42 ("Such an approach is described by Winters, et al., in U.S. Pat. Nos. 5,182,317; 5,262,451 and 5,338,770 in which the amine functional groups of the active material are covalently bonded using a polyethylene oxide (PEO) on a siloxane surface."); col. 2:43-46 ("Another approach is described in U.S. Pat. No. 4,613,665 to Larm in which heparin is chemically covalently bound to impart a non-thrombogenic surface to the material."); col. 3:19-27 ("Accordingly, it is a primary object of the present invention to provide a coating and process for coating a stent to be used as a deployed stent prosthesis, the coating being capable of effective controlled long-term delivery of

biologically active materials. Another object of the invention is to provide a coating and process for coating a stent prostheses using a biostable hydrophobic elastomer in which biologically active species are incorporated within a coating."); col. 6:16-27 ("The mechanism of incorporation of the biologically active species into the surface coating and egress mechanism depend both on the nature of the surface coating polymer and the material to be incorporated. The mechanism of release also depends on the mode of incorporation. The material may elute via interparticle paths or be administered via transport or diffusion through the encapsulating material itself."); col. 6:28-34; col. 6:35-48; col. 10:35-40 ("In addition, because of the negative charges on the heparin itself, the electro-negativity of the fluorosilicone topcoat may be, at least in part, responsible for the modified heparin release kinetic profile."); col. 12:62-67 ("Whereas the polymer of the coating may be any biostable elastomeric material capable of being adhered to the stent material as a thin layer, hydrophobic materials are preferred because it has been found that the release of the biologically active species can generally be more predictably controlled with such materials. Preferred materials include silicone rubber elastomers and biostable polyurethanes specifically.").

Dinh '227: Col. 2:26-32; col. 3:10-14; col. 5:53-55 ("Suitable polymers could also be biodegradable polymers such as polyphosphate ester, polyhydroxybutyrate valerate, polyhydroxybutyrate-co-hydroxyvalerate and the like."); col. 6:13-22; col. 6:32-50; col. 6:50-56; col. 7:10-13 ("The adhesion of the coating and the rate at which the drug is delivered can be controlled by the selection of an appropriate bioabsorbable or biostable polymer and by the ratio of drug to polymer in the solution."); col. 7:13-23; col. 7:30-44; col. 7:45-51 ("The polymer used can be bioabsorbable or biostable polymer. Suitable bioabsorbable polymers include poly(L-lactic acid), poly(lactide-co-glycolide) and poly(hydroxybutyrate-co-valerate). Suitable biostable polymers include silicones, polyurethanes, polyesters, vinyl homopolymers and copolymers, acrylate homopolymers and copolymers, polyethers and cellulose."); col. 9:17-18; col. 12:38-50.

[Domb '055: Abstract ("Preferred polymeric coatings are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); col. 3:54-62 ("In the preferred embodiments, these have utilized bioerodible polymers as the matrix for the drug to be released, usually as a function of diffusion and erosion of the polymer. The advantage of these drug delivery systems is that they provide a sustained/continuous release of drugs locally and at a relatively high concentration in areas of the body, without systemic side-effects, throughout the duration of their release."); col. 4:11-13 ("It is a further object of the present invention to provide medical devices having prolonged low-dose, localized release of anti-microbial and anti-inflammatory agents."); col. 4:33-36; col. 5:27-33; col. 5:41-45 ("The drug-loaded polymer provides a sustained release of steroids and antibiotics locally and at a relatively high concentration in that area which is critically affected, without the side-effects of the systemic administration of the same drugs, throughout the duration of intubation."); col. 5:49-54; col. 5:60-6:1 ("An esophageal silicone stent coated with a film of polymer can be used to provide a site-specific controlled release of corticosteroids and antibiotics."); col. 6:3-7; col. 6:24-26 ("Examples of suitable polymers include ethylene vinyl acetate, polyurethane, silicones, hydrogels, polyurethane, and polyvinyl chloride."); col. 6:42-45 ("Release is a function of diffusion of the agent from the polymeric matrix, and varies by size, concentration and solubility of the agent, as well as by thickness and

chemical composition of the polymeric matrix."); col. 7:10-20; col. 7:25-29; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 11:36-38 ("The medical device of claim 1, wherein the polymer is selected from the group consisting of polyurethane, ethylene vinyl acetate, silicones, hydrogels, and polyvinyl chloride."); col. 11:39-44; col. 12:1-7; col. 12:11-22; col. 12:23-25; col. 12:26-31; col. 12:32-42.

Fox '096: Abstract ("A method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers, and antimicrobial agents . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 3:55-67 ("The polymeric coating agent component of the coating vehicle of the present invention is selected from the group consisting of biomedical polyurethanes, biomedical silicones, biodegradable polymers and combinations thereof."); col. 4:30-5:35; col. 7:22-25; col. 7:28-32; col. 11:34-48 ("Suitable biodegradable polymers include the homopolymers poly(glycolic acid), poly(D-lactic acid), poly(D,L-lactic acid), poly(D,L-ethyl-glycolic acid), poly(dimethylglycolic acid), poly(D,L-methylethylglycolic acid), and poly(E-caprolactone), as well as biodegradable polyhydroxy butyric acid and mixtures thereof. A preferred biodegradable polymer is polylactic acid (PLA)."); col. 11:51-56 ("The biodegradable polymer modulates the rate of release of antimicrobial drugs."); Table IV; col. 12:24-41 ("Suitable biomedical poly(lactic) polymers include the poly(L-lactide), poly(D-lactide) and the poly (D-L-lactic acid). . . . The poly(lactic acid) polymers are bioerodible, and while they can be used alone, it is preferred that they be combined with either a biomedical polyurethane or a biomedical silicone."); col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages."); col. 18:19-25; col. 20:54-58; col. 28:13-18; col. 29:38-40 (Adding a biodegradable material containing anti-microbial agents to the adhesive to provide controlled-release through degradation."); col. 36:21-31; col. 36:47-51; col. 36:65-37:7; col. 37:29-31; col. 37:56-57; col. 37:63-65; col. 37:66-38:9; col. 38:24-30; col. 39:39-41; col. 40:33-34; col. 40:39-42.

Hunter '981: Abstract; col. 3:42-61 ("A wide variety of molecules may be utilized within the scope of the present invention as anti-angiogenic factors, including for example Anti-Invasive Factor, retinoic acids and their derivatives, paclitaxel including analogues and

derivatives thereof, Suramin, Tissue Inhibitor of Metalloproteinase-1, Tissue Inhibitor-1 and Plasminogen Activator Inhibitor-2, and lighter "d group" transition metals. Similarly, a wide variety of polymeric carriers may be utilized, representative examples of which include poly (ethylene-vinyl acetate) (40% cross-linked), poly (D,L-lactic acid) oligomers and polymers, poly (L-lactic acid) oligomers and polymers, poly(glycolic acid), copolymers of lactic acid and glycolic acid, poly(caprolactone), poly(valerolactone), poly(anhydrides), copolymers of poly(caprolactone) or poly(lactic acid) with polyethylene glycol, and blends thereof."); col. 5:27-32; col. 12:23-35 ("As noted above, the present invention provides compositions comprising an anti-angiogenic factor, and a polymeric carrier."); col. 16:31-56 ("[A]nti-angiogenic compositions of the present invention are provided in a wide variety of polymeric carriers, including for example both biodegradable and non-biodegradable compositions. Representative examples of biodegradable compositions include albumin, gelatin, starch, cellulose, dextrans, polysaccharides, fibrinogen, poly (D,L lactide), poly (D,L-lactide-co-glycolide), poly (glycolide), poly (hydroxybutyrate), poly (alkylcarbonate) and poly (orthoesters) Representative examples of nondegradable polymers include EVA copolymers, siliconerubber and poly (methylmethacrylate). Particularly preferred polymeric carriers include poly (ethylene-vinyl acetate)(40% cross-linked), poly(D,L-lactic acid) oligomers and polymers, poly (L-lactic acid) oligomers and polymers, poly (glycolic acid), copolymers of lactic acid and glycolic acid, poly (caprolactone), poly (valerolactone), polyanhydrides, copolymers of poly (caprolactone) or poly (lactic acid) with polyethylene glycol and blends thereof."); col. 16:31-56; col. 16:66-17:6 ("Anti-angiogenic factors may be linked by occlusion in the matrices of the polymer, bound by covalent linkages, or encapsulated in microcapsules. Within certain preferred embodiments of the invention, anti-angiogenic compositions are provided in non-capsular formulations such as microspheres . . . pastes, threads of various size, films and sprays."); col. 17:7-26; col. 17:41-43 ("Anti-angiogenic compositions may also be prepared, given the disclosure provided herein, for a variety of other applications."); col. 18:15-49 ("Within further aspects of the present invention, polymeric carriers are provided which are adapted to contain and release a hydrophobic compound, the carrier containing the hydrophobic compound in combination with a carbohydrate, protein or polypeptide. Within certain embodiments, the polymeric carrier contains or comprises regions, pockets, or granules of one or more hydrophobic compounds."); col. 47:58-49:7; col. 56:45-57; col. 57:17-31; col. 59:65-60:48; col. 59: 32-59 ("Poly(e-caprolactone) is an aliphatic polyester which can be degraded by hydrolysis under physiological conditions and it is non-toxic and tissue compatible."); col. 69:19-62; col. 77:43-55 ("The release of paclitaxel, in this case, is dominated by polymer degradation."); col. 78:58-79:5 ("Although not specifically set forth above, a wide variety of other polymeric carriers may be manufactured, including for example . . ."); col. 84:62-86:24; col. 86:60-67.

Kinsella '608: Col. 11:18-24 ("Drug delivery systems that can be valuable include drug-impregnated polymer-coated metallic stents [and] biodegradable drug-eluting polymer stents . . .").

Kowligi '782: Col. 4:16-27 ("In regard to elastomeric coating 38 shown in Fig. 2, such elastomeric coating is selected to be a biocompatible elastomers and may be selected from the group consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 10:18-27; col. 10:28-32 ("The implantable vascular graft recited by claim 1 wherein said elastomers is selected from the group

of elastomers consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 10:43-50; col. 10:60-67.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 1:46-55 ("Release of heparin from intravascular catheters in quantities sufficient to decrease thrombosis on the catheter has been achieved by either covalently bonding a charged molecule to a polymer or incorporating a large nonmobile charged molecule on the surface of the polymer . . ."); col. 1:62-65; col. 2:16-35; col. 2:40-50 ("In accordance with the present invention, there is provided a method for preparing a system suitable for localized delivery of biologically active compounds to a subject."); col. 2:55-67; col. 3:8-12; col. 3:29-49; col. 4:10-17; col. 7:29-32; col. 7:38-41; col. 8:62-9:19 ("Adventitia overlying the stent contained 360 times the concentration of forskolin in the blood and 305 times the concentration of forskolin in the contralateral artery. . . . In a similar model, etretinate, a retinoic acid analog, develops concentrations in the media of 250 ng/mg tissue at 24 hours. At 24 hours, this concentration was over 2000 times the concentration in the blood."); col. 9:31-37 ("These data demonstrate that a polyurethane coated nitinol stent is capable of delivering a lipophilic drug in high local concentration in the vessel wall. The large 450 fold differential of local tissue levels of forskolin over blood levels reflects the capability of this delivery system to provide high local concentration and potentially higher efficacy, with lower risk of systemic side effects."); col. 12:21-22 ("The method in accordance with claim 1, wherein the biologically active compound is a lipophilic compound."); col. 12:27-30 ("The method in accordance with claim 1, wherein the biologically active compound is a hydrophilic compound, said method further comprising linking the hydrophilic compound to a lipophilic carrier.").

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p. 2:10-19 ("Release of heparin from intravascular catheters in quantities sufficient to decrease thrombosis on the catheter has been achieved by either covalently bonding a charged molecule to a polymer or incorporating a large nonmobile charged molecule on the surface of the polymer . . ."); p. 2:25-30; p. 3:10-31 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); p. 4:2-12; p. 4:17-31; p. 15:25-16:14 ("Adventitia overlying the stent contained 360 times the concentration of forskolin in the blood and 305 times the concentration of forskolin in the contralateral artery. . . . In a similar model, etretinate, a retinoic acid analog, develops concentrations in the media of 250 ng/mg tissue at 24 hours. At 24 hours, this concentration was over 2000 times the concentration in the blood."); p.16:27-34 ("These data demonstrate that a polyurethane coated nitinol stent is capable of delivering a lipophilic drug in high local concentration in the vessel wall. The large 450 fold differential of local tissue levels of forskolin over blood levels reflects the capability of this delivery system to provide high local

concentration and potentially higher efficacy, with lower risk of systemic side effects."); claim 14 ("The method in accordance with claim 1, wherein the biologically active compound is a lipophilic compound."); claim 16 ("The method in accordance with claim 1, wherein the biologically active compound is a hydrophilic compound, said method further comprising linking the hydrophilic compound to a lipophilic carrier."); claim 26.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8; p. 1:56-58.

Mitchell '711: Col. 6:24-28 ("Suitable solid carrier include, for example, calcium phosphate, magnesium stearate, talc, sugars, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, sodium carboxymethyl cellulose, polyvinylpyrrolidone, low melting waxes and ion exchange resins.").

Morris '781: Col. 10:50-54 ("Suitable solid carriers include, for example, calcium phosphate, magnesium stearate, talc, sugars, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, sodium carboxymethyl cellulose, polyvinylpyrrolidone, low melting waxes and ion exchange resins.").

Morris '182: Page 6:54-56 ("Suitable solid carriers include, for example, calcium phosphate, magnesium stearate, talc, sugars, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, sodium carboxymethyl cellulose, polyvinylpyrrolidone, low melting waxes and ion exchange resins.").

Myler '563: Col. 4:57-59; col. 4:60-67 ("[T]he stent can be provided with a solid drug carrier such as an impregnated porous solid wall or sponge for timed drug delivery."); col. 5:39-41 ("For the above reasons, even the expanded pores for drug delivery should be small enough to maximize or prevent cell penetration, but large enough for drug delivery."); col. 13:15-18 ("The exterior coating which will contact the arterial wall is optionally made porous to enable the release of drugs to the treatment site.").

Palmaz '417: Col. 11:8-11; col. 11:26-34 ("Examples of biologically compatible coatings would include coatings made of absorbable polymers such as those used to manufacture absorbable sutures. Such absorbable polymers include polyglycoides, polyacoides, and copolymers thereof. Such absorbable polymers could also contain various types of drugs, whereby as the coating is absorbed, or dissolves, the drug would be slowly released into the body passageway.").

Tice '330: Col. 3:20-33 ("A preferred group of polymeric wall forming materials includes those which are biodegradable such as aliphatic polyesters including polylactide, polyglycolide, polycaprolactone and copolymers thereof."); col. 8:38-51.

Thies '317: Abstract ("The capsules provide controlled release of the active agent over a prolonged period of time."); col.1:15-19 ("The art of encapsulation has developed various processes and methods for individually coating particular matter for purposes of controlled release or metering out of an active agent over a prolonged period."); col. 2:26-38; col. 2:43-47;

col. 2: 48-51; col. 3:41-4:2; col. 6:35-39 ("Therefore, the presence of a soluble alkali metal silicate in the interior of the capsule causes much of the capsule coating material to simply disappear upon immersion in water thereby causing accelerated release of the active agent."); col. 7:36-11:68; col. 12:10-40; col. 13:4-14:3.

Tice '840: Col. 2:32-34; col. 2:38-55 ("The polymeric matrix material of the microparticles of the present invention must be a biocompatible and biodegradable polymeric material. . . . Suitable examples of polymeric matrix materials include poly (glycolic acid), poly-d,l-lactic acid, copolymers thereof, copolyoxalates, polycaprolactone, poly (lactic acid-caprolactone), and the like."); col. 2:56-3:8 ("The molecular weight of a polymer is also important from the point of view that molecular weight influences the biodegradation rate of the polymer. The drug can also be released from the microparticles as the polymeric excipient bioerodes. By an appropriate selection of polymeric materials a microparticle formulation can be made such that the resulting microparticles exhibit both diffusional release and biodegradation release properties."); col. 10:56-11:15; col. 12:6-9.

Tice '025: Col. 2:32-34; col. 2:38-55 ("The polymeric matrix material of the microparticles of the present invention must be a biocompatible and biodegradable polymeric material. . . . Suitable examples of polymeric matrix materials include poly (glycolic acid), poly-d,l-lactic acid, copolymers thereof, copolyoxalates, polycaprolactone, poly (lactic acid-caprolactone), and the like."); col. 2:56-3:8 ("The molecular weight of a polymer is also important from the point of view that molecular weight influences the biodegradation rate of the polymer. The drug can also be released from the microparticles as the polymeric excipient bioerodes. By an appropriate selection of polymeric materials a microparticle formulation can be made such that the resulting microparticles exhibit both diffusional release and biodegradation release properties."); col. 10:51-11:5; col. 12:1-4.

Lapka '244: Abstract; col. 2:35-63; col. 4:35-57 ("Among the bioabsorbable polymer materials suitable for use in the invention may be mentioned poly(lactic acid) or polylactic acid polymers, such as dl-poly(lactic acid) (or poly(dl-lactic acid)) polymers, poly-(glycolic acid) polymers, poly(hydroxybutyric acid) polymers and lactide/glycolid copolymers."); col. 4:58-5:5 ("The solid injectable drug material which constitutes the core material of the microcapsules may be any such injectable drug material for which it is desired to establish a long-acting, sustained release delivery system."); col. 32:5-16; col. 32:20-21; col. 32:28-34; col. 32:35-39 ("The process according to claim 8 wherein the core material is selected from the group consisting of cyclazocine, tetracycline, ehtisterone, digitoxin, antimony potassium tartrate, salmon calcitonin, ACTH, lypressin, sommatostatin, and insulin.").

Kent '189: Abstract; col. 1:12-28 ("The invention relates to a microcapsule composition comprising a core containing at least one water-soluble, hormonally active polypeptide and optionally a polymer hydrolysis modifying agent encapsulated in a biodegradable, biocompatible copolymer excipient. These compositions have sustained release characteristics. More specifically it relates to microcapsules wherein the core contains water-soluble polypeptides which are lutenizing hormone-releasing hormones, or mammalian growth hormones or polypeptides having thymosin-like activity and optionally an organic acid or its salts, or an acidic, neutral or basic inorganic salt which is capable of modifying the hydrolysis rate of the

polymer excipient, encapsulated by a biocompatible, biodegradable excipient."); col. 1:50-58; col. 2:4-7 ("The encapsulating material may be a synthetic polymer comprising either poly(o-hydroxycarboxylic acids), poly(lactones), poly(acetals), poly(orthoesters) or poly(orthocarbonates)."); col. 11:5-38; col. 11:39-13:35 ("The number and type of encapsulating excipients which may be effectively used to practice this invention is limited only by the requirements that the material be biocompatible and biodegradable. . . . Various combinations of alpha hydroxycarboxylic acids and certain lactones can be condensed to form such polymers, particularly lactic acid and glycolic acid or combinations thereof. . . . Similar biocompatible polymers based on glycolic acid and glycerol and the like are also known. . . . Several new biocompatible, biodegradable polymers derived from polyorthoesters and polyorthocarbonates also may be effectively used as encapsulating excipients in the practice of this invention. . . . There are also known polyacetals and polyorthoesters useful for this purpose . . ."); col. 17:42-18:67.

Tice '268: Abstract ("A compatible, biodegradable microcapsule delivery system for active ingredients, including hormonally active peptides, proteins, or other bioactive molecules . . ."); col. 1:32-46 ("More recently a polymer of poly(D,L-lactide-co-glycolide) (DL-PLG), which is biodegradable and biocompatible with living tissue, has been used in microcapsules for longer acting delivery systems. Systems of microencapsulated active ingredients in polymers and copolymers have been used to achieve controlled release of chemical and biological pharmaceuticals."); col. 1:47-2:14 ("The microcapsule systems described in the above-publications all share a common feature in that the release of the compound is controlled by the porosity and/or erosion of a polymer continuum."); col. 2:45-53; col. 3:40-47 ("It should be noted, however, that other polymers besides poly(D,L-lactide-co-glycolide) may be used. Examples of such polymers include, but are not limited to: polyacetal polymers, polyorthoesters, polyesteramides, polycaprolactone and copolymers thereof, polycarbonates, polyhydroxybuterate and copolymers thereof, polymaleamides, copolyaxalates and polysaccharides."); col. 11:15-41.

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); col. 3:13-18; col. 3:34-38 ("In a preferred technique, one or more finishing coats of a second solution containing the same or another biocompatible polymer without the carrier is applied to provide an impermeable or substantially less permeable outer surface."); col. 4:29-34 ("In this embodiment, active factor 26 is incorporated within the membrane wall 12. The outer membrane surface 28 is nonporous, while porous inner membrane surface 22 allows for the diffusion therethrough of active factor 26."); col. 4:66-5:11 ("The membrane of the channel may be fabricated from any biocompatible polymers, such as, for example, polyethylene vinyl-acetate (EVA). . . . Preferable acrylates include methacrylates or hydroethylmethacrylates. The membrane instead may be composed of a bioresorbable biocompatible polymer, such as a polyanhydride, polyester, or mixtures thereof."); col. 5:18-28 ("In a preferred embodiment of the invention, the outer surface of the membrane is impermeable to solutes of any size, while the inner membrane surface contains pores [that] enable the active factors to diffuse out of the membrane and into the lumen of the channel."); col. 5:44-6:10; col. 6:17-22 ("The layering procedure allows deposition of an impermeable coat on the outer surface of the device, insuring that the active factors incorporated into the membrane walls will be inhibited from diffusing

through the external surface, and will diffuse only through the inner membrane surface into the lumen of the channel."); col. 9:18-10:3; col. 10:10-12.

Folkman '560: Col. 1:56-2:23; col. 2:43-68; col. 3:18-23 ("The polymer matrixes, which are suitably used in the present invention, are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:36-51 ("Typical polymeric material suitable for forming the matrix . . . include . . . alkylene-vinyl acetate copolymers . . . crosslinked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:52-4:26 ("In the presently preferred embodiment the polymeric materials useful for forming the matrix are the ethylene vinyl ester copolymers of the general formula . . ."); col. 8:17-18; col. 11:56-12:20; col. 12:28-31; col. 12:36-43; col. 12:52-54 ("The therapeutic system for the administration of insulin according to claim 1, wherein the polymeric matrix is ethylene-vinyl acetate copolymer."); col. 12:59-61.

Cohen '496: Abstract; col. 2:46-66 ("In general, the invention features an improved method of making such a body, in which a biologically active material and the polymer below the glass transition temperature of the polymer and compressing the mixture above the glass transition point of the polymer. In preferred embodiments, the polymer is an ethylene-vinyl ester copolymer of the general formula . . ."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:65-4:39 ("In a presently preferred embodiment, the polymeric materials useful for forming the matrix are the ethylenevinyl ester copolymers of the general formula . . ."); col. 9:40-10:17; col. 10:18-32.

Schiraldi '243: Col. 1:58-60 ("Other polymers that might be added are vinyl copolymers, polysaccharides, gelatin and collagen."); col. 2:30-51; col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 3:14-34; col. 4:67-5:27; col. 10:3-7; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Helwing '868: Abstract ("The compositions may either be in capped form or leashed to a polymeric backbone. . . . The primary uses of the compositions are in controlled release applications such as drugs . . . or in any application where predictable hydrolytic release of the active agent is desirable."); col. 1:6-16 ("The present invention relates generally to compositions

of matter and more particularly to covalently bonded compounds composed of active agents containing reactive functional groups The primary uses of the invention are in hydrolysable controlled release utilizations of active agents in such areas as pharmaceuticals, insecticides, herbicides, and the like."); col. 1:19-37 ("In addition . . . it may be highly desirable to have a system that permits the continuous controlled release of an agent . . ."); col. 1:38-2:11 ("One of the most common methods of achieving predictable controlled release mechanism of an active chemical agent is to encapsulate the agent with another material which gradually degrades in the desired medium. . . . A similar method is to trap molecules of the active agent within a surrounding polymer matrix. The matrix structure is such that exposure to an environmental material, usually water, causes the matrix structure to gradually degrade until the surrounding matrix structure is decomposed to the extent that the active agent molecule is permitted to escape into the environment. . . . The Heller, et al. patent utilizes a polymer structure . . . subject to hydrolysis, that is, it is subject to degradation in a gradual manner upon contact with water."); col. 2:12-24 ("The usefulness of structures such as that taught in Heller, et al. patent is significantly dependent upon the unique bioerodable, or hydrolysable, bonding structure . . ."); col. 2:25-37 ("The bonds so formed between the ketene acetals or vinyl ethers and hydroxyl groups are readily hydrolysable under even mildly acidic conditions. It is postulated that similar results will be obtained between various other functional groups on active agents and ketene acetals or vinyl ethers, and that these linkages will be hydrolysable with degradation of the covalent bond in the presence of water providing an ideal mechanism for controlled release of chemical or biological agents."); col. 38-53 ("In the present invention, as active agents will be bonded directly to the controlled release matrix, specific structural design of the base component system will most directly affect control over the hydrophobicity of the overall matrix."); col. 2:55-3:27; col. 3:37-43 ("It is an object of the present invention to provide an aggregation of useful chemical compounds wherein a chemically active agent via its polar active (PA) functional groups is covalently bonded with a carbonium ion mechanism ("CIM") base group, the bond therebetween being hydrolysable in a predictable manner, resulting in controlled release."); col. 3:47-50; col. 3:62-66; col.3:67-4:17 ("The present invention is an aggregation of compositions consisting of a hydrolysable covalent bond formed between a base structure and an active agent structure. . . . The combinations are particularly adapted for use in controlled release of the active agents by way of hydrolysis. The usefulness of the combinations of the present invention is found in a wide degree of chemical and biological applications including drugs . . ."); col. 4:18-38 ("The inventive compositions of matter have the common property that the covalent bond joining the active agent to the base component is predictably hydrolyzable."); col. 4:39-5:6; col. 5:7-46; col. 5:47-50 ("An advantage of the present invention is that new compositions of matter may be created which are subject to predictable hydrolysis under selected environmental conditions."); col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20 ("Each of the compositions of the present invention has two distinct moieties joined by a hydrolyzable covalent bond. . . . The active component will have this chemical or biological effect when it is in its free molecular form but will not have the same effect when it is restricted in the inventive composition by the covalent bond. The hydrolytic decomposition of the covalent bond will act to release the agent so that it may again act in its original molecular form."); col. 7:21-8:50 ("Polymeric support substrates for the leashed systems would include polyvinyl alcohol, dextran, cellulose and similar polyhydroxy polymers."); col. 8:51-9:29 ("The common thread found in the various active agents is that each include one or more functional PA subgroups which are capable of forming the desired hydrolyzable covalent bond with the CIM

subgroups of the base component in a predictable manner."); col. 9:30-52 ("With respect to other active agent functional PA groups and CIM base components, the bond structure will not be a pure orthoester linkage but will be of a similar hydrolyzable nature."); col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48 ("However, in the presence of water, the orthoester-type linkage is subject to hydrolysis as shown in equation EQ-2 and the Z group representing either the ketene acetal or thioacetal."); col. 12:49-13:5 ("The hydrophobicity of the inventive compositions may be altered such that the composition hydrolyzes at different rates."); col. 19:57 ("As is clear from the above, the scope of possible compositions that can be created according to the present invention is extremely broad. . . . All of the inventive compositions are such that they may be created by the process of the present invention and all will be similar in that the CIM and PA groups will form a hydrolyzable covalent bond which will act to keep the inventive composition intact under environmental conditions until hydrolysis occurs."); col. 20:18-37 ("Timed-release drugs for controlled introduction into the blood stream or other body tissues or cavities are well known, including compositions referred to as pro-drugs. The inventive compositions are extremely well adapted for use in this field. . . . Along these lines, the inventive systems could be used to deliver not only general drugs, but cancer drugs, hormones, vitamins, fungicides and even used as a more durable sunscreen."); col. 20:46-54; col. 20:55-68 ("The preferred embodiment of the present invention may also be applied to a surface as a film of uniform consistency for use in several areas of application. . . . The chemically linked nature of the controlled release matrix affords not only the ability to apply such films, but permits the most compact physical structuring possible in a controlled release matrix as well as an assured even distribution of the desired agent."); col. 21:27-41; col. 21:42-46 ("The composition of claim 1 wherein said covalent bond is predictably degradable via hydrolysis such that the active agent component may be released in a controlled release manner under selected environmental conditions."); col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3 ("The composition of claim 1 wherein the covalent bond is destructible via hydrolysis at a predictable reaction rate in a specified environment to yield a hydrolytically degraded base component and the active component as separate molecules."); col. 23:4-col. 24:27.

Valentini '029: Col. 3:15-25 ("The semipermeable nerve guidance channels of the present invention can also be biodegradable.").

Greco '135: Abstract; col. 1:19-26 ("This invention relates to methodology for the surface modification of surgical implants permitting the binding of drugs which, after implantation, are slowly released. More particularly, this invention relates to improved surgical implants having sustained, localized delivery of pharmacological agents such as extended antibiotic activity or reduced thrombogenicity, and methods for producing same."); col. 1:29-2:59 ("The surface modification of surgical implants by the adhesion of pharmacological agents for the purpose of minimizing infection and prosthesis rejection is well-known and has generated broad interest for some time. . . . The present Application is therefore an effort to further disclose and particularize this aspect of the invention, i.e., the development of the antibiotic bonded prosthesis utilizing an anionic surfactant and the oppositely charged drug, antibiotic or other agent or factor."); col. 3:8-19 ("An object of the present invention is to provide improved surfactant-modified implantable devices having a drug, including antibiotics, antithrombogenic agents, thrombolytic agents, disinfectants, etc., bound to the surface thereof. . . . Another object of the present invention is to provide an improved implantable device having a drug bound

thereto of improved release times."); col. 3:22-27; col. 3:30-43; col. 4:2-39; col. 5:30-6:58 (disclosing process by which antibodies can be bound to thermoplastic substrates); col. 7:46-9:3; col. 9:10-12.

Bawa '279: Abstract; col. 1:16-36; col. 2:27-35 ("With the foregoing and other objects in view, the invention herein provides a sustained-release polymeric hydrogel dosage form useful for topical, systemic or transdermal administration of a medicinal agent comprising one or more polymerizable hydrophilic polymers, an ion-exchange resin, a cross-linking agent and optionally one or more hydrophobic polymers."); col. 2:39-46; col. 2:47-68 ("The preferred hydrophilic monomers are the hydroxyalkyl esters, specifically hydroxyethyl methacrylate (HEMA)."); col. 4:14-25; col. 6:40-44 ("The invention contemplates a variety of processes for preparing the sustained-release polymeric hydrogel dosage form whereby the medicinal agent is retained by the polymeric matrix and, upon tissue contact, is gradually released into the tissue."); col. 7:15-21; col. 8:1-6; col. 8:29-49; col. 8:54-55; col. 8:66-68; col. 11:42-54; col. 13:10-17; col. 13:26-14:14.

Aebischer '627: Col. 3:23-49 ("In addition, these polymeric materials have the capacity for sustained release of the embedded substance at a controlled rate."); col. 3:57-4:3 ("The polymeric insert includes pores having a molecular weight exclusion of from about 1 kD to about 1,000 kD, but preferably from about 25kD to about 100 kD. In one preferred embodiment, the polymeric insert includes a hydrophobic matrix such as ethylene-vinyl acetate copolymer."); col. 6:52-59 ("the insert may be composed of any biocompatible material having the desired pore size and being composed of materials which do not limit the activity of the substance embedded therein. . . . [H]ydrophobic matrices such as ethylene vinyl acetate are particularly useful."); col. 7:3-12 ("One way of providing the source of neurotransmitter include incorporating it into the polymeric insert. The encapsulating material provides a protective environment for substances such as neurotransmitters or cell growth factors embedded therein, while affording sustained release of the substance at a controlled rate therefrom."); col. 7:13-28; col. 7:29-56 ("The release rate may also be controlled by the amount of pure, impermeably polymeric material coating the effector substance-embedded insert; the more (or thicker the) coatings, the slower the release rate. Materials such as polyurethane or pure ethylene-vinyl acetate are particularly useful for this purpose."); col. 10:31-34 ("To retard dopamine release, three coats of 10% EVAc were applied to each rod by repeated immersion . . ."); col. 14:29-32; col. 14:45-49; col. 14:57-58.

Wood '066: Abstract ("A controlled-release bandage containing therapeutic agents in a poly(vinyl alcohol) cryogel is disclosed. The bandage may include . . . hydrophobic particles to further insure controlled and constant release of therapeutic agents."); col. 2:56-66 ("Bandages comprising cryogel and therapeutic agents are used to provide a protective covering and to provide a controlled and uniform administration of therapeutic agents to sites of trauma such as wound, thermal or chemical burns, ulcers, lesions or surgical sites. Cryogel bandages may include . . . particles having hydrophobic properties, which absorb the therapeutic agent and release it in an uniform and controlled manner."); col. 3:47-4:36; col. 7:6-32 ("The release of therapeutic agents from the bandage has been found to be further controllable by including insoluble particles capable of adsorbing or forming salts with the therapeutic agent in the bandage. . . . Other examples of suitable insoluble particles include hydrophobic resins, silica, hydroxyl apatite and aluminum oxide."); col. 7:43-50; col. 8:55-56; col. 26:8-18 ("The bandage

of claim 1 wherein the insoluble particles capable of adsorbing or forming salts with the therapeutic agent are a hydrophobic resin particles.").

Strecker '746: Abstract; col. 1:63-2:2; col. 2:21-32; col. 3:5-17 ("Another sensible advanced version is characterized in that medications in the lining are dissolved in the wrapping material or included in the form of beads."), ("It can be practical for there to be more or less openings in the wall of the lining next to the lumen than there are in the wall next to the inner surface of the vessel. The ratio can be exploited to prescribe the dosage of medication to the lumen or wall of the blood vessel."); col. 3:17-26 ("The wrapping material can also to advantage be biodegradable When the material is biodegradable, the medication will be released not by diffusing out of the vehicle but by escaping as the vehicle that the medication is dissolved in or that accommodates the beads that encapsulate the medication at its surface decomposes and by accordingly coming into contact with body fluids."); col. 3:27-33; col. 5:10-12; col. 5:38-41; col. 6:1-17; col. 6:35-38; col. 7:16-37 ("a lining impregnated with medication for delivery to a wall of said body lumen"); col. 7:48-65; col. 8:19-10:19; Figs. 7 & 8.

Lambert '246: Abstract ("The biologically active compound is, therefore, released only at the site where it is desired, i.e., where the prosthetic article is positioned."); col. 1:46-55 ("Release of heparin from intravascular catheters in quantities sufficient to decrease thrombosis on the catheter has been achieved by either covalently bonding a charged molecule to a polymer or incorporating a large nonmobile charged molecule on the surface of the polymer . . ."); col. 1:57-61; col. 2:15-34 ("Increasing the lipid solubility of the compound slows release from the polyurethane, and increases the tissue retention. More lipid soluble compounds are, therefore, preferred agents for use in the practice of the present invention."); col. 2:38-40 ("In accordance with the present invention, there is provided a method for preparing a system suitable for localized delivery of biologically active compounds to a subject."); col. 2:40-49; col. 2:53-65; col. 7:31-33 ("The results of this example demonstrate that polyurethane stent coatings can concentrate and release lipophilic drugs in vitro."); col. 8:58-9:4 ("Adventitia overlying the stent contained 360 times the concentration of forskolin in the blood and 305 times the concentration of forskolin in the contralateral artery. . . . In a similar model, etretinate, a retinoic acid analog, develops concentrations in the media of 250 ng/mg tissue at 24 hours. At 24 hours, this concentration was over 2000 times the concentration in the blood."); col. 9:31-37 ("These data demonstrate that a polyurethane coated nitinol stent is capable of delivering a lipophilic drug in high local concentration in the vessel wall. The large 450 fold differential of local tissue levels of forskolin over blood levels reflects the capability of this delivery system to provide high local concentration and potentially higher efficacy, with lower risk of systemic side effects."); col. 10:47-50; col. 10:62-64 ("The drug delivery system of claim 1 wherein the biological agent is absorbed substantially throughout the entire thickness of the polyurethane elastomer coating."); col. 11:16-17 ("The drug delivery system of claim 8, wherein said biologically active compound is a lipophilic compound."); col. 11:30-31; col. 11:36-40; col. 12:12-13; col. 12:17-21; col. 12:53-54.

Bellamkonda '029: Col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this

invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 5:32-48 ("The agarose hydrogels of this invention may be used as a carrier to present various ECM proteins or peptides We prefer covalent immobilization of ECM proteins to the hydrogel backbone."); col. 7:26-32 ("In a preferred embodiment, laminin-derived oligopeptidic fragments . . . are coupled to the hydroxyl backbone of agarose, using any suitable method."); col. 9:36-48 ("These growth factors may be incorporated into the channel membrane . . ."); col. 11:7-8 ("Additionally, the membrane may be composed of a biodegradable material."); col. 11:41-50; col. 12:13-16 ("Preferably the permselective membrane is fabricated to be impermeable to some of these substances so that they are retained in the proximity of the regenerating nerve ends."); col. 12:42-49; col. 12:50-56; col. 15:67-16:17; col. 23:54-24:55.

Dayton '382: Abstract ("The stent is then coated with a polymer . . . which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids, with the equilibrium being controlled by charge distribution, concentration and molecular weight of the bioactive substance in relation to the pore size of the polymeric carrier for controlled prolonged release of said bioactive substance."); col. 1:9-17 ("The present invention relates to an improved percutaneously inserted endoprosthesis device which is permanently or temporarily implanted within a body vessel, typically a blood vessel. More particularly, the present invention relates to a new procedure for administering localized bioactive substances via prosthesis designs . . ."); col. 3:36-39; col. 3:62-4:17 ("Among these polymers are polymers having a microporous structure, such as . . . biodegradable polylactic acid polymers, polyglycolic acid polymers . . ."); col. 4:24-33 ("A bioactive substance is preferably admixed in the polymer for elution from the microporous structure of the stent or coating on the stent after implantation. The rate of elution of the bioactive substance is controlled by selecting a pore size for microporous structure . . ."); col. 6:64-7:7 ("Also included in the polymer is a bioactive substance having a charge distribution, concentration and molecular weight selected which achieves an equilibrium in relation to the pore size of the polymeric carrier with said surrounding body tissues or fluids."); col. 7:8-14; col. 7:20-23.

Burt '036: p.4:19-33 ("Within one aspect of the present invention, compositions are provided . . . comprising (a) an anti-angiogenic factor and (b) a polymeric carrier. A wide variety of molecules may be utilized within the scope of the present invention as anti-angiogenic factors Similarly a wide variety of polymeric carriers may be utilized, representative examples of which include poly(ethylene-vinyl acetate) . . . and copolymers of polylactic acid and polycaprolactone."); p.10:17-25; p.14:9-27; p.21:2-4; p.51:1-52:35.

Goldin '568: Abstract; col. 1:21-34 ("In certain circumstances, another desirable use of controlled release methods is to target the delivery of a therapeutic agent specifically to the tissue or site that can benefit from the presence of such an agent."); col. 1:35-41 ("Several classes of controlled release strategies have been developed, principally involving: (a) release by controlled diffusion; . . . and (c) release limited by chemical control of the interaction of the agent with a substrate to which it is adsorbed or bound."); col. 1:43-62 ("Release by controlled diffusion may be accomplished by means of containment of the therapeutic agent within a substrate whose small pore size and/or tortuosity of diffusion path thereof limits the diffusion of said agent through the substrate. . . . The therapeutic agent can be incorporated within the diffusion-

limiting substrate Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:8-16 ("Towards that end, diffusion-controlled slow release devices have been fabricated from biodegradable polymers . . ."); col. 2:24-28; col. 3:42-53 ("Release by chemical control most commonly involves chemical cleavage from a substrate to which a therapeutic agent is immobilized, and/or by biodegradation of the polymer to which the agent is immobilized."); col. 3:54-65 ("Another variant of release by chemical control termed herein "controlled noncovalent dissociation or 'CND'", relates to release resulting from dissociation of an agent that is bound temporarily by non-covalent binding of the agent to a substrate."); col. 4:25-45 ("The microskin is specifically tailored to bind macromolecules . . . noncovalently by cooperative secondary bonds, and slowly release the macromolecules by controlled non-covalent dissociation (CND)"); col. 4:63-66; col. 6:1-19 ("Because preferred embodiments of the CND controlled Release Device and methods of use thereof employ membranes whose pore size is normally much greater than molecular dimensions, the kinetics of release are governed primarily by the strength and number of the reversible cooperative secondary bonds which immobilize said protein for CND."); col. 6:20-29 ("Limitation of the toxicity associated with the macromolecules to be released results from selective delivery to the site of action in the amounts and at the time needed. While in practice, the temporal and spatial selectivity of the current invention may not be absolute, it is clearly an improvement over more conventional modes of delivery . . ."); Fig. 1A; Fig. 1B; col. 8:65-9:6; col. 9:18-22; col. 9:23-30; col. 9:43-50 (" . . . delivery from controlled release devices can be controlled by diffusion out of said device, dissociation of chemical bonds, and the like."); col. 9:51-55; col. 10:45-54; col. 17:40-54 ("[S]ynthetic polymers . . . may be derivatized to attach functional groups which may react under appropriate circumstances to form covalent bonds with the macromolecules one wishes to bind and release in a controlled manner."); col. 20:9-12 ("By appropriate use of said Device, one can selectively target a therapeutic site . . ."); col. 20:46-21:19 ("[W]hen the pore size of the underlayment and/or the microskin approaches submicron dimensions and/or the thickness of said Devices approaches millimeter dimensions or greater, diffusion of the agent to be delivered out of said device may contribute to or even be the predominant process governing controlled release from said Device."); col. 21:47-49 ("A coating of a permeable guide tube, with a secondary membrane designed to exclude macromolecules from without."); col. 27:10-18; col. 32:26-31.

Palmaz '762: Col. 10: 28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '337: Col. 9: 24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Zaffaroni '254: col. 2:6-9 ("Still another approach has been to enclose the drug within a single capsule having a polymeric wall or walls through which the drug can pass, for example, by diffusion."); col. 2:16-26 ("Additionally, these prior art devices have generally been based on the use of a single material, such as silicone rubber polymers, especially polydimethylsiloxane,

as the diffusion control membrane. In large part, these polymers were selected because of their permeability to some important drug molecules. But, it has been found that mere high permeability without consideration of release rate controlling properties can be a significant disadvantage which defeats the primary object of an acceptable drug delivery device."); col. 4:54-58 ("In operation, solid drug carrier 13 serves as a reservoir 12 by supplying dissolved drug 14 to the micropores 15 of wall 11 as drug molecules move through the carrier to bathe the inner surface of wall 11."); col. 7:18-25.

Langer I: p.29 ("In the bioerodible system, the drug is distributed relatively uniformly throughout the plastic as in matrix systems, but it differs from the matrix in that its plastic portion decreases with time. As the plastic surrounding the drug is eroded, the drug escapes. . . . The most popular bioerodible polymers have been absorbable suture materials such as polylactic acid."); p.29-30 ("The second type of chemically controlled system is known as a pendant chain system. In simplest form, the drug is attached via chemical bonds to a polymer backbone. It could also be attached via a spacer group Release occurs when water reacts to break those bonds, thereby freeing the drug. Release rates are adjusted by varying the hydrophilicity of the polymer backbone. Systems could also be designed so that an enzymatic reaction could break the drug-polymer bonds."); p.29 Figure legend ("Chemically controlled pendant chain drug-delivery system. Here, the drug is bound to a polymer backbone and released by hyd[r]olytic or enzymatic cleavage, the key to controlling the medication's delivery.").

Langer II: p.217-18 ("In chemically controlled systems, release is accomplished either by biodegradation of the polymer . . . or by chemical cleavage of the drug from a polymer backbone to which the drug had been bound as a pendent group."); p.218 Fig. 3; p.219 Fig. 4 ("Chemically controlled pendent-chain drug-delivery system. Here, the drug is bound to a polymer backbone and released by hydrolytic or enzymatic cleavage."); p.221-225 ("Contraception" "Immunization" "Anticoagulation" "Cancer" "Insulin Delivery" "Controlled-release formulations may be applied to other clinical areas, including the release of narcotic antagonists, antibiotics, interferons, anesthetics, anti-arrhythmics, and antimalarial drugs.").

Langer III: p.25 ("Matrix Systems"); p.26-27 ("From a chemical standpoint, Heller has considered bioerodible systems in terms of three dissolution mechanisms: [1] water-soluble polymers insolubilized by degradable cross-links; [2] water-insoluble polymers solubilized by hydrolysis, ionization, or protonation of pendant side-groups; and [3] water-soluble molecules. These mechanisms represent extreme cases, and erosion by a combination of mechanisms is possible."); Fig. 3-3; Fig. 3-4; p.27-28 ("In pendant chain systems, a drug is chemically bound to a polymer backbone-chain and is released by hydrolytic or enzymatic cleavage. . . . The polymer system can be either soluble or insoluble . . . insoluble forms are more desirable for long-term controlled-release implants. The backbone may also be biodegradable or nonbiodegradable. . . . The drug itself can be attached directly to the polymer or attached via a spacer group. The spacer group may be used to affect the rate of release and hydrophilicity of the system.").

Langer & Peppas: Fig. 5; p.80-83 ("Matrix Systems"); p.83 ("Polymers for Diffusion-Controlled Systems"); p.84; p.85 ("Ethylene-vinyl acetate (EVAc) copolymers have found major applications in controlled release of bioactive agents because of their relatively good chemical stability, biocompatibility, and inertness."); Fig. 7; p.86-87 ("Chemically controlled drug release

generally involves one of two types of systems: 1) Erodeable systems in which the drug is dispersed in a biodegradable polymer and drug release is influenced by the rate of degradation of the polymeric material, and 2) pendant chain systems in which the drug is attached to a polymer through a hydrolytically or enzymatically labile linkage. Drug release is influenced by the rate of degradation of this linkage."); Fig. 8; p.87-100 (describing and identifying polymers for biodegradable drug release systems); p.100-101 ("In [pendant chain systems] a drug is chemically bound to a polymer backbone and is released by hydrolytic or enzymatic cleavage. . . . [I]nsoluble [backbones] are more desirable for long-term controlled-release implants. . . . The drug itself can be attached directly to the polymer or it can be attached via a spacer group. The spacer group may be used to affect the rate of release and hydrophilicity of the system. To achieve near constant release, the cleavage of the drug from the polymer must be the rate-limiting step. . . . There has recently been interest in developing controlled-release systems using pendant chain polymers for clinical applications."); p.114-16 ("Medical applications of controlled-release systems can be divided into four general areas: oral systems, transdermal systems, external implants, and subcutaneous implants.").

Langer IV: p.36 ("In matrix systems, the drug is uniformly distributed through a polymer."); Fig. 2; p.37 ("Two systems of chemical control exist. The first mechanism is bioerosion or biodegradation of the polymer. As the polymer surrounding the drug is eroded, the drug escapes. . . . The second type of chemically controlled system is known as a pendant chain system. In simplest form, the drug is attached via chemical bonds to a polymer backbone. It could also be attached via a spacer group. Release rates are adjusted by varying the hydrophilicity of the polymer backbone. Systems could also be designed so that an enzymatic reaction could break the drug-polymer bonds."); p.37 Fig. 3 ("Idealized diagram of the cross-section of a cylindrical or spherical bioerodeable matrix."); p.37 Fig. 4 ("Idealized diagram of a chemically controlled pendant chain drug delivery system. The drug could be connected to the polymer backbone as shown or could be coupled to a spacer group attached to the polymer backbone."); p.41-42 ("The second type of [contraceptive] system is a subdermal implant composed of a biodegradable polymer."); p.44 ("Small (0.3 mm³) injectable pellets of ethylene-vinyl acetate copolymer containing 100 ug of a test antigen, bovine serum albumin, were positioned subcutaneously in mice.").

Langer V: p.24 ("Examples of polymers with these properties include nondegradable polymers such as ethylene-vinyl acetate copolymers (EVAc), and biodegradable polymers such as polylactic or polyglycolic acid.") ("Theoretically, the [biodegradable] polymers should have a hydrophobic backbone, but with water-labile linkage.").

Langer VI: p.115 (One approach that has received increasing attention as a means of prolonging drug release has been the incorporation of drugs in solid polymers (e.g., silicone rubber, ethylene-vinylacetate copolymer). This method permits drugs to be released for long time periods in a controlled fashion."); p.120-124 ("The ideal [biodegradable] polymer would have a hydrophobic backbone, but with water labile linkage.").

Laurencin & Langer: Fig. 2; p.304-306 ("Matrix Systems"); p.306-307 ("Three dissolution mechanisms for bioerodeable polymeric devices are found in general: Type 1: water soluble polymers that are made insoluble through crosslinks that are degradable. On exposure to

an aqueous environment, crosslinks are broken, polymer dissolves, and release occurs. Type 2: water insoluble polymers that on exposure to an aqueous environment are solubilized by hydrolysis, ionization, or protonation of pendant side groups. Type 3: water insoluble polymers containing hydrolytically unstable backbone linkages. On exposure to an aqueous environment, polymer chains are cleaved to small water soluble monomers."); p.307 Fig. 4; p.308-309 ("In [pendant chain systems], drug is chemically bound to the backbone of a polymer. Release takes place by hydrolytic or enzymatic cleavage. . . . Polymer systems can be soluble or insoluble, and the backbone itself may be bioerodible or nonbioerodible. Soluble backbone chains are generally used for transport functions such as cell targeting; insoluble forms are more desirable for long-term controlled release implants. Drug can be chemically attached to the polymer directly or through a spacer group. The spacer group may be used to affect the rate of release or hydrophilicity of the system."); p.308 Fig. 5 ("Chemically controlled pendant chain drug delivery device. Drug bound to polymer backbone is released by hydrolytic or enzymatic cleavage."); p.313-316 (clinical applications of EVAc and biodegradable polymers).

Langer VII: p.1529 ("Chemical control is accomplished either by polymer degradation or chemical cleavage of the drug from a polymer."); p.1529 Fig.1(B), (C) and (D); p.1530 ("Examples of polymers that perform in this way are non-degradable ethylene-vinyl acetate copolymer and degradable lactic acid-glycolic acid copolymers."); p.1531-32 ("Theoretically, the [ideal surface-eroding] polymer should be hydrophobic but should have water-labile linkages.").

Langer & Moses: p.341-42 ("[W]e proposed that an ideal polymer would have a hydrophobic backbone, but with a water labile linkage."); p.342-44 ("One such report . . . employed the porous ethylene-vinyl acetate copolymer (EVAc) system to provide sustained release of fibroblast growth factor (FGF) or epidermal growth factor (EGF).").

Chien: p.32-33 ("[The hydrolysis-activated] controlled drug delivery system depends on the hydrolysis process to activate the release of drug molecules. . . . The release of a drug from the polymer matrix is activated by the hydrolysis-induced degradation of polymer chains and controlled by the rate of polymer degradation.") ("[The enzyme-activated] controlled drug delivery system depends on the enzymatic process to activate the release of drug. . . . The release of drugs is activated by the enzymatic hydrolysis of the biopolymers by a specific enzyme in the target tissue."); p.37 ("An ideal site-targeting drug delivery system has been proposed . . . constructed from a nonimmunogenic and biodegradable polymer backbone having . . . a drug moiety that is covalently [sic] bonded to the polymer backbone through a spacer and contains a cleavable [sic] group that can be cleaved only by a specific enzyme(s) at the target tissue.").

Thomson: p.34-36 ("The degradation of synthetic polymers is, in general, brought about by simple hydrolysis, although in some cases enzymatic processes assist in the degradation mechanism.").

Hanes & Langer: p. 647 ("Polymers can also be used to deliver vaccines in a controlled manner."); p.648 ("Biodegradable polymeric devices or pendant chain systems are examples of chemically controlled devices. In the former, molecules are typically dissolved or entrapped in a biodegradable, bioresorbable polymer matrix As the polymer degrades and erodes,

molecules are released to the surroundings. In pendant chain systems, molecules are chemically attached to the backbone of a polymeric carrier using hydrolytically or enzymatically degradable bonds. In this case, the molecules are liberated as the bonds holding them to the polymer are cleaved."); p.649 Fig. 29.2; p. 652 ("For the present development of vaccine delivery systems, the use of biodegradable polymers presents significant advantages over the use of nondegradable systems."); p.654-55 ("There are many such polymers that may prove useful for controlled delivery of vaccines; however, no degradable polymer systems has been more widely studied with respect to release kinetics than the lactide/glycolide polyesters."); p.655-56; p.656-58 ("Advantages of Controlled Release for Immunization").

Batz: p.26-27 ("Based on their chemical structure polymeric drugs are divided into the following three groups . . . b) Drugs in which the active substance of known biological activity is bound to a polymeric carrier molecule via a functional group."); p.36-43 ("Polymeric drugs formed by covalent bond of known active components to soluble macromolecular carriers"); p.48 ("Polymeric Forms of Deposit Without Covalent Bond Between Drugs and Polymeric Materials.").

Donaruma: p.10 ("Allan, Chopra, Neogi, and Wilkins, in studies concerned with the design and synthesis of controlled release pesticide polymer combinations, investigated the duration of effectiveness of various herbicidal phenoxyacetic acids chemically bound as pendant substitutes to natural or synthetic water-soluble and water-insoluble polymers."); p.17, 19-20 ("[I]t can be seen that in some cases portions of the polymer repeat unit are structurally constituted so that by hydrolysis the polymer chain or a pendant group may be sundered by hydrolysis. . . . Chemically combining a drug in a polymer may offer a means of sustained release and/or prolonged activity of drugs and/or drug latentiation. These are not new concepts, and examples are reported in the literature.").

Harris I: p.334 ("As reported in this review, our work has involved the syntheses and evaluation of polymers containing pendant aquatic herbicides."); p.344 ("The herbicide release rates of polymers containing herbicides as pendant substituents are extremely slow in water with pH=C at 30°C. The herbicide release rates, however, can be increased by incorporating hydrophilic groups along the polymers' backbones").

Feld: p.113-15 ("One approach to obtaining these formulations has been the synthesis of polymers that contain pesticides as pendent side chains. . . . Pesticide release occurs by the slow, sequential hydrolysis of the pesticide-polymer chemical bonds. This provides a sustained release of the pesticide over an extended period of time. The actual release depends on the nature of the pesticide polymer bond and the dimensions and structure of the resultant macromolecular combination."); p.116-17 ("It was postulated that increasing the length of the pendent side chain would enhance the hydrolysis of the herbicide-polymer bond."); 117-19 ("Herbicide reactivation was produced enzymatically using lipase, acetylcholinesterase and trypsin.").

Harris & Post I: p.622 ("One approach to obtaining controlled-release pesticide formulations that contain a high percentage of pesticide has been the synthesis of polymers that contain pesticides as pendent side chains. The pesticide is presumably released by the slow sequential hydrolysis of the pesticide-polymer chemical bonds. . . . It was postulated that

increasing the length of the pendent side chain would enhance the hydrolysis of the herbicide-polymer bond.").

Harris & Post II: p.225 ("One approach to obtaining controlled-release pesticide formulations that contain a high percentage of pesticide has been the synthesis of polymers that contain pesticides as pendent side chains. The pesticide is presumably released by the slow sequential hydrolysis of the pesticide-polymer chemical bonds. . . . It was postulated that increasing the length of the pendent side chain would enhance the hydrolysis of the herbicide-polymer bond.").

Drobnik: p.2833 ("Water-soluble copolymers based on poly[N-(2-hydroxypropyl)methacrylamide] and bearing in their side chains a chromogenic substrate for chymotrypsin were prepared by direct copolymerization or polymeranalogous reaction."); p.2834 ("The bonding of drugs onto macromolecules is an old idea, because it offers a potential optimization of the pharmacokinetics of drugs. The majority of pharmaceuticals are inactive in the macromolecular form and must, therefore, be released in their original active low-molecular weight form, i.e. their attachment to the polymer must be reversible, or degradable."); p.2844-47 ("The results also indicate the general influence of the spacer: the longer the spacer, the easier the cleavage of the enzyme susceptibility bound For practical purposes, that is, enzyme-specific binding of drugs to polymers, the following conclusions can be drawn from the above results . . .").

Allan I: p.17 ("These materials are chemical or physical combinations of known and established pesticides with macromolecules. . . . As the pesticide-polymer combination lies in the soil, a gradual decomposition occurs, and the pesticide is slowly released over the desired and predictable period of time."); p.18-19 ("This situation is avoided by the use of a chemical combination of the butyric acid [herbicide] with the polymeric components of bark. The ester linkage joining the herbicide to the bark will not be easily attacked by any β -oxidase and the butyric acid herbicide is thereby stabilized. Essentially, the only butyric acid herbicide available for β -oxidation is that continuously being released from the bark. This release will occur whether the combination lies in or on the surface of the soil since attack by moisture, micro-organisms and the weather can occur in either of these zones.").

Allan II: p.349 ("We have therefore investigated the potential of pesticide-polymer combinations as a means of securing controlled release of a biodegradable pesticide in approximately the correct amount needed over an appropriate period of time. . . . Two distinct approaches are not reported. (a) Pesticide release by diffusion through polymers, and (b) pesticide release by degradation of a polymer containing the pesticide as a pendent side chain. . . . For case (b) the pesticides . . . are chemically attached as a pendent substituent to a natural or synthetic water-soluble or insoluble polymer . . ."); p.350 ("In the biological environment, side chain degradation occurs so that the chemical bonds holding the pesticide within its polymeric prison are sequentially broken to provide a sustained release of the pesticide over an extended period of time. The rate of release will clearly be determined by the nature of the pesticide-polymer bonds, the chemical characteristics of the pesticide and polymer and the dimensions and structure of the resultant macromolecular combination.") ("Although developed for developed

for forest pest control the systems described should be broadly applicable to the controlled release of other biologically active substances.").

Allan III: p.173: ("Controlled release from polymeric matrix"); p.173-74 ("Representative of the other end of the thermodynamic spectrum is the situation where the pesticide is firmly attached to the substrate by a high energy covalent bond. Release of the pesticide then involves the cleavage of a definite identifiable chemical bond such as an ester or amide. . . . The simplest [arrangement] has the pesticide attached as a pendent substituent to a natural or synthetic water-soluble or insoluble polymer having a replaceable hydrogen The chemical bonds holding the pesticide within its polymeric prison are sequentially broken to provide a sustained liberation of the pesticide over an extended period of time."); p. 176 ("Moreover, the [controlled release] concept is broadly applicable to the release of other biologically active substances.").

Jakubke: p. 281 ("Observations in our laboratory indicated that an enzymatic cleavage of carrier-bound biologically active substance of low molecular weight is fundamentally possible. As part of a general model study of enzymatic reactions with insoluble substrates we investigated the α -chymotrypsin-catalyzed hydrolysis of Sepharose-bound L-phenylalanine 4-nitroanilide. As a spacer, 1 or 2 mol of 6-amino-hexanoic acid, respectively, were inserted between the gel matrix and the low-molecular weight substrate."); p. 282 ("The course of hydrolysis was proportional to time during the first 15 min. About 70% of total bound (ϵ Ahx)₂-Phe-NA was hydrolyzed after 4 hr."); Fig. 2 ("Dependence of hydrolysis on the enzyme concentration at 25°C."); p. 283 ("In agreement with this the substrate dependence of the hydrolysis rate shows the same course as observed with Glt-Phe-NA.").

Engelberg & Kohn: p. 292 ("For example, degradable polymers are now being investigated as intra-luminal grafts, stent-like devices that are implanted into coronary arteries in an attempt to prevent the collapse and the reblocking (restenosis) of blood vessels after successful balloon angioplasty."); p.293 ("Since surface-eroding, slab-like devices tend to release drugs embedded within the polymer at a constant rate, poly(ortho esters) appear to be particularly useful for controlled release drug delivery. It is not surprising that there are a significant number of publications describing the use of poly(ortho esters) for drug delivery applications."); p. 293-94 ("PLA, PGA and their copolymers are also being intensively investigated for a large number of drug-delivery applications. . . . PLA, PGA and their copolymers are currently the most widely used synthetic degradable polymers in human medicine."); p.294, Table 1; 294-95 (The potential applications of these [PHB polymers] include biomedical applications such as controlled drug release . . ."); p.295 ("Later, it was discovered that PCL can also be degraded by a hydrolytic mechanism under physiological conditions. Under certain circumstances, cross-linked PCL can be degraded enzymatically, leading to enzymatic surface erosion."); p.296 ("It is interesting to note that despite its versatility, PCL has so far been predominantly considered for controlled-release drug-delivery applications.") ("The low hydrolytic stability] was later recognized as a potential advantage by Langer et al. who suggested the use of polyanhydrides as degradable biomaterials."); p. 297; p. 298 ("Poly(ortho esters)"); p. 298-99 ("PGA"); p. 299 ("PLA"); p. 300 ("PBH and copolymers with HV"); p. 301 ("PCL") ("Because of their low mechanical strength and high hydrolytic reactivity, the two polyanhydrides tested appear to be limited to drug-delivery applications."); p. 302.

Roseman & Mansdorf: p. 91-105 ("The objective of this chapter is to describe the development of a bioerodible polymer implant that would release an incorporated drug by zero-order kinetics for at least 6 months. A further objective is the development of a system where drug release and polymer erosion take place concomitantly so that no polymer remains when the drug is depleted."); p. 107 ("There have been, however, studies where polymer-drug complexes have been synthesized, the major objective of which was to provide a controlled or prolonged action of the drug by the natural hydrolysis or biological scission of the covalent polymer-drug bond. In this way, mescaline, insulin, salicylic acid, D-isoproterenol, naloxone, plant cytokinins, 2,4-dichlorophenoxyacetic acid, norethindrone, and cortisol-21-acetate have been attached to and released from various synthetic and natural polymers through covalent bonds such as amide, ester, aso, carbamate, carbonate, oxime ester, and hydrazone."); p. 108 ("GAGs are biodegradable by enzymatic means normal to the host."); 108-109 ("We have taken advantage of various types of functional groups available on the GAG backbone (carboxyl, primary and secondary hydroxyl, and sulfate) in preparing and testing a series of complexes in which the drug was bound directly to the polymer or via an intermediate linking group such as an amino acid or other such bioacceptable entity. . . . Current work with other drugs bound to the GAG backbone by the same and different bond types (i.e., carbamate, ionic) will be reported in the near future."); p.110; p. 111 ("Amide and ester bond types were chosen because both are susceptible to chemical hydrolysis and both are prevalent naturally and thus are potentially dependable by enzymes."); p. 112 Fig. 2 & 3; p. 112-113 ("The release was pseudo-first order with a release rate constant of 0.10 day^{-1} and a half-life of 3.8 days. This is what one would expect if the rate-determining stem for release is the chemical hydrolysis of the ester bond in the prodrug."); p. 113 ("Reactions on polymers, such as the hydrolytic cleavage of GAG-drug bonds, has been shown to be affected by polymer chain length and conformation, steric isolation, and neighboring group effects."); p. 114; p. 115 ("Even though the amid bond between the drug and the polymer may hydrolyze slowly over this period and release cysteine, the rate-determining step for release was probably enzymatic breakdown of the complex. . . . A large advantage of using glycosaminoglycans as drug carriers is that they are biocompatible and biodegradable."); p.116 ("Chloramphenicol-GAG ester complexes released Cpl quickly by scission of the ester bond. Cysteine-GAG amide complexes degraded much more slowly and probably through enzymatic hydrolysis of the polymer or polymer-drug bond."); p. 117 ("Nevertheless, this concept provides an interesting base from which to design a drug release system; the rate of release may in principle be engineered by the judicious choice of drug-GAG bond based on the hydrolytic stability of the bond.").

Lee & Good: p. 2; p. 2-3 ("As a result of research on improved absorbable sutures, poly (lactic acid), poly (glycolic acid), and lactic/glycolic acid copolymers, which hydrolyze to natural metabolites, have been developed for drug delivery purposes."); p. 3 ("[P]olymer erosion can be controlled by the following three types of mechanisms: (1) water-soluble polymers insolubilized by hydrolytically unstable cross-links; (2) water-insoluble polymers solubilized by hydrolysis, ionization, or protonation of pendant groups; (2) hydrophobic polymers solubilized by backbone cleavage to small water soluble molecules. . . . [O]ther commonly used bioerodible/biodegradable polymers include polyorthoesters, polycaprolactone, polyaminoacids, polyanhydrides, and half esters of methyl vinyl ether-maleic anhydride copolymers.") ("Drug-Polymer conjugates. This system involve drug molecules chemically bounded to a polymer backbone. The drug will be released through hydrolytic or enzymatic cleavage. . . . The

attachment of drugs to macromolecular carriers alters their rate of excretion from the body and provides the possibility for controlled release over a prolonged period. . . . Both natural polymers such as polysaccharides and synthetic polymers such as polylysine, polyglutamic acid, polyphosphazenes, copolymers of vinylpyrrolidone, copolymers of 2-hydroxypropylmethacrylamide, and etc. have been used as drug carriers."); p. 4 ("The drug-polymer linkage may be covalent, ionic, or through some weaker secondary molecular forces. The drug may be part of the polymeric backbone or attached to the side-chain either directly or through a spacer group. The spacer groups is generally selected in such a way that it may be hydrolyzed or degraded enzymatically under specific environmental conditions. Examples of such drug-polymer conjugates include the attachment of ampicillin, 6-amino-methacrylamide copolymers, methotrexate to poly (L-lysine), and norethindrone to poly(hydroxyalkyl)-L-glutamine. In addition to diffusion rate limitations as described in the next section, the drug release rate is primarily governed by the rate of cleavage of the drug from the polymer."); p.5- 7 ("Matrix Diffusion"); p. 7 ("Polymer Erosion. The release of a dissolved or dispersed drug from an erodible polymer matrix can be controlled by a variety of mechanisms ranging from hydrolysis/enzymatic cleavage as discussed in the previous section to swelling and dissolution."); p. 17 ("An important example of these processes is the controlled release of bioactive molecules from polymeric membranes. Many pharmaceutically active agents have been released at controlled rates from hydrophobic polymer carriers. . . . In 1976 it was demonstrated that hydrophobic polymers, in particular ethylene-vinyl acetate copolymer (EVAc), could be used to release molecules with molecular weights greater than 1000."); p. 182 ("Enzyme-Degradable Hydrogel"); p.188-200; p. 214-230.

Langer & Folkman I: p. 179 ("Therefore, we turned to other polymers such as ethylene-vinyl acetate copolymer . . ."); p. 180-83; p. 183-84 ("Poly(vinylalcohol), Hydron, and ethylene-vinyl acetate copolymer were examined for their ability to release soybean trypsin inhibitor . . ."); p. 185-88; col. 188-191 ("The following three studies demonstrate that the pellets are releasing macromolecules in biologically active form."); p. 191-92 ("The present experiments show that macromolecules with a wide range of molecular weights can be delivered in significant quantities from polymeric vehicles that are not inflammatory when implanted in animals. These polymers can release macromolecules in biochemically and biologically active form for periods in excess of 100 days as measured by direct assays. . . . The eventual clinical application of these polymers for delivery of macromolecules such as insulin, heparin, or enzymes may merit consideration.").

Langer & Folkman II: p. 798-99 ("Polyvinylalcohol, Hydron and ethylene-vinyl acetate copolymer were examined for the ability to release soybean trypsin inhibitor . . .") ("These studies show that sustained release of proteins and other macromolecules from polymeric vehicles can be achieved over prolonged periods.").

Langer VIII: p. 1 ("One approach that has received increasing attention as a means of prolonging drug release has been the incorporation of drugs in solid polymers (e.g. silicone rubber, ethylene-vinyl acetate copolymer). This method permits drugs to be released for long time periods in a *controlled* fashion."); p. 10 ("Controlled-release polymer formulations may also find applications in other clinical areas. One such area that has received increasing attention is the controlled release of antibiotics. . . . Polymers have also been used to deliver anesthetics,

anti-malarial drugs, anticoagulants, and drugs to combat cardiac arrhythmia."); p. 27 ("However, several recent studies have demonstrated that matrix systems can be engineered to permit continuous release of large molecules. By solvent casting normally impermeable polymers such as ethylene-vinyl acetate copolymer in volatile solvents . . . along with powdered macromolecule, a series of interconnecting channels is formed within the polymer matrix. . . . These macromolecular delivery systems now open the possibility of delivering many important large molecular weight compounds such as insulin or interferon for prolonged periods."); Fig. 20; p. 28-29 ("[T]he volume of bioerodible systems becomes smaller with time, and, as the polymer surrounding the drug is eroded, the drug escapes."); p. 30 ("Erosion could be caused by hydrolytic or enzymatic cleavage of the crosslinks so that the ultimate degradation products are high molecular weight polymers. Alternatively, the degradation could occur in the polymer backbone so that the degradation products have low molecular weights."); p. 31-32 ("The third category of biodegradable systems are water-insoluble polymers that undergo hydrolytic or enzymatic backbone cleavage and are solubilized to small water-soluble molecules. . . . The best example of this class of polymer is polylactic acid or copolymers of lactic acid and glycolic acid."); p. 32 ("Sidman and coworkers . . . developed a peptide copolymer of glutamic acid and ethyl-*L*-glutamate."); p. 32-34 ("Pendant Chain Systems: In this type of system, a drug is chemically bound to a polymer backbone and is released by hydrolytic or enzymatic cleavage. The use of these therapeutic agents has received considerable attention in drug-related research. The major thrust so far has been the design of polymer-drug complexes for short-term use that can reduce toxicity, increase therapeutic efficiency, or be targeted towards specific cells or organs. . . . The drug itself can be attached directly to the polymer or it can be attached via a spacer group. The spacer group may be used to affect the rate of release and the hydrophilicity of the system. . . . To achieve near constant release, the cleavage of the drug from the polymer must be the rate-limiting step."); Fig. 22.

Langer & Folkman III: p. 114-15; p.117-18 ("Demonstration of Long-term Release") ("In initial trials with soybean trypsin inhibitor . . . protein was released . . . least rapidly from ethylene-vinylacetate copolymer."); p. 119-20 ("When tested in this fashion, ethylene-vinylacetate copolymer pellets continued to produce zones on these slides for over 100 days, indicating that the pellets were releasing nearly 1 ug/day or biochemically active protein."); p. 123-25 ("Insulin Delivery"); p. 125-26 ("Immunization Procedures").

Rhine: p. 265 ("Matrixes composed of ethylene-vinyl acetate copolymers are useful vehicles for the sustained release of macromolecules such as proteins These polymer systems had uniform drug distribution, and their release kinetics were reproducible."); p. 267 ("Therefore, macromolecules were added to a solution of polymer dissolved in a volatile solvent (methylene chloride). This mixture, when cast and dried, produced matrixes capable of sustained macromolecular release. . . . The reproducibility of release kinetics for matrixes prepared by low temperature methods was demonstrated for different proteins and for a range of particle sizes and loadings."); p. 268 ("A coating can also be used to control macromolecular release kinetics."); p. 269 ("Clinically, these systems may prove valuable as single-step methods for immunization or for the continuous delivery of insulin and other high molecular weight drugs.").

Aebischer: p. 282-83 ("Chemically inert polymer matrices, allowing controlled release of entrapped macromolecules over long time periods . . . open a new avenue of investigation. . . . The solvents used appear to have no detrimental effects on the biological activity of a number of growth factors."); p. 283 ("Channel Fabrication"); p. 283 (disclosing the use of an impermeable outer coating which results in directional release of the treating factors into the lumen of the device); Table 1; p.286 ("The present study demonstrates that ethylene vinyl acetate copolymer can be fabricated into tubes with adequate physical properties for nerve entubulation and allows the controlled release of macromolecules.").

Langer IX: p.267 ("Two polymers suitable for sustained macromolecular release, poly(hydroxyethyl methacrylate), and alcohol-washed ethylene-vinyl acetate copolymer, were noninflammatory.") ("[W]e provide documentation that two polymers suitable for sustained macromolecular release, poly(hydroxyethyl methacrylate) (polyHEMA) and alcohol-washed ethylene-vinyl acetate copolymer, possess a high degree of biocompatibility in the rabbit cornea."); p.269; Table 1; p.276.

Langer X: p.179-80 ("Although we investigated several polymeric systems, the best results from the standpoint of tissue biocompatibility and long-term release (>100 days) were obtained with ethylene-vinyl acetate copolymer."); p.180 ("Biocompatibility studies"); p.181-87 ("In vitro and in vivo release kinetics"); p.192 ("Possible mechanisms of release of macromolecules") ("The absence of effect of ionic strength (fig7) suggests that osmotic pressure or charge interactions of drug with polymer have negligible roles in affecting release rates."); p. 195-200 ("Here, four studies exploring biomedical uses of these polymer systems are discussed. These include: (1) insulin delivery systems, (2) vehicles for immunization, (3) interferon delivery systems, and (4) systems for delivering anticancer or antiangiogenic macromolecules.").

Langer XI: p.95-96 ("Recent studies in our laboratory have demonstrated, however, that solvent casting of a variety of polymeric materials (ethylene-vinyl acetate copolymer, polyvinylalcohol, poly-2-hydroxymethyl-methacrylate) in the presence of powdered drug permits continuous release of macromolecules for over 100 days.").

Brown: p.1181 ("Macromolecules such as enzymes, antigens, and insulin have been released in biologically active form [from ethylene-vinyl acetate copolymers] for up to 6 months *in vivo*."); p. 1184 ("These data show that *in vivo* release can be accounted for by the same mechanisms operating *in vitro*; this should now make possible the further development and increased use of ethylene-vinyl acetate copolymer drug delivery systems.").

Kost & Langer: p.47-48 ("Bioerodible controlled systems."); p.48-49 ("Applications").

Hsu & Langer: p. 445-46 ("The current study shows the MW of EVAc copolymer is as important as drug loading and drug particle size in affecting the drug release kinetics. A release mechanism, which includes the properties of the polymer carrier, is proposed to serve as a guideline in selecting a suitable EVAc polymer carrier for a particular drug release device."); p.459.

Bawa: p.259 ("For example, EVAc polymers have been used as . . . delivery systems for insulin, interferon, and antigens."); p.263 ("Minimal effects exist due to osmosis or charge

interaction of the drug with the polymer."); p.266 ("The data should be useful in the design of release vehicles for various polypeptides, polysaccharides, and other bioactive agents now produced by genetic engineering.").

Leong & Langer: p.202; p.203 ("The two common chemically controlled systems are a biodegradable matrix in which the drug is dispersed, and a polymer-drug conjugate in which the drug molecules are linked to the side chains of the polymer."); p.206-209 (describing use of biodegradable polymers for contraceptive systems); p.210-11 ("Against Ehrlich ascites carcinoma in rats, a sustained release of 5-fluorouracil from poly(ethylenevinylalcohol) is more efficacious than free drug administration."); p.211-14 ("Pendant systems"); p. 214-15 (use of EVAc for hormonal therapy and angiogenesis inhibition); 219-23 ("The clear demonstration of the feasibility [of sustained release of insulin from polymer] was later provided by a study using poly(ethylenevinylacetate) (EVAc).").

Baker: p.14-15 ("Diffusion-Controlled Monolithic Systems"); p.15-16 ("Biodegradable Systems"); 161-65 ("Poly(ethylene vinyl acetate)").

Langer XII: p.162 ("In chemically controlled systems, release is accomplished either by biodegradation of the polymer or by chemical cleavage of the drug from a polymer backbone on which the drug had been bound as a pendant group."); p.163 ("A variety of reservoir and matrix devices are prepared from swollen crosslinked hydrophilic polymers (hydrogels). Most successful devices of this kind are based on poly (2-hydroxyethyl methacrylate) (HEMA) and related polymers although hydrophilic homopolymers of (poly vinyl 1-2-pyrrolidone) (PNVP), poly (vinyl alcohol) (PVA) and copolymers thereof have been tested with considerable success.") ("Ethylene-vinyl acetate (EVA) copolymers are prepared by emulsion copolymerization of ethylene and vinyl acetate. They are soluble in organic solvents and they can be used to prepare films or rods of dimensional stability and good mechanical strength."); p. 163-64 ("Biodegradable Polymers"); 164-67 (clinical uses for controlled-release polymer systems).

Langer XIII: p.166; p.170 ("Studies have also been conducted to explore numerous applications of these systems. These include release of insulin . . . , anti-calcification agents . . . , interferons . . . , growth factors . . . and inhibitors . . . , and neurologically active agents.").

Chasin: p.43-44 ("In designing a biodegradable system that would erode in a controlled heterogeneous manner without requiring any additives, we have suggested that due to the high lability of the anhydride linkage, polyanhydrides may be promising candidates."); p.45 ("Molding procedures"); p.47-62 ("Kinetics of Drug Release") (describing release of various compounds); p.66-68 (polyanhydride safety and clinical studies).

Langer XIV: p.538-40 (describing polymers used in controlled release systems, including cellulose, poly(glycolic acid) and poly(lactic acid), poly(ortho esters), polyanhydrides, silicone rubber, ethylene-vinyl acetate copolymer, and poly(2-hydroxyethyl methacrylate)); 540-42 (describing clinical uses for controlled release systems).

Brem: p.2 ("The ethylene-vinyl acetate copolymer (EVAc) is an example of a non-biodegradable polymer while poly[bis(p-carboxyphenoxy) propane-sebacic acid] copolymer (PCPP-SA) and the fatty acid dimmer-sebacic acid copolymer (FAD-SA) are examples of

biodegradable polymers."); p.3 ("Clinical applications for the EVAc polymer include drug delivery for contraception, insulin therapy, cancer chemotherapy, glaucoma treatment, dental caries prevention, and asthma therapy."); p.4-6 (describing in vivo and clinical studies of PCPP-SA and EVAc based delivery of chemotherapeutic drugs).

Langer XV: p.102 ("Our best long-term release results were obtained with relatively hydrophobic polymers, such as ethylene-vinyl acetate co-polymer or lactic glycolic acid copolymer, using methylene chloride as a casting solvent."); p.105 ("Therefore, we proposed to initiate studies on the development of a new class of bioerodible polymers: polyanhydrides."); p. 109 ("Through the NH₂ groups of lysine, specific amino acid sequences such as arginine-lysine-aspartic acid (RGD) have been chemically coupled to polylactic acid-co-lysine.").

Thompson: p.31-32; p.32 ("In this article, we include hydrolysis and enzymatic degradation under the heading of biodegradative processes."); p. 32-33 ("Collagen is one of the most widely used and best characterized of the natural biomaterials"); p.33 ("Gelatin, cross-linked with formaldehyde, has been studied in vitro as a drug delivery matrix . . ."); p.33-34 ("Starch"); p. 34 ("Furthermore, because of its hydrophilicity, cellulose has been utilized in pharmaceutical formulations to enhance water uptake and improve drug delivery.") ("The degradation of synthetic polymers is, in general, brought about by simply hydrolysis, although in some cases enzymatic processes assist in the degradation mechanism."); p.35 ("Since . . . the degradation characteristics of [poly(glycolic acid)] are predictable and reproducible, PGA has become a material of choice for many proposed applications calling for a synthetic biodegradable polymer.") ("Poly(L-lactic acid)"); p. 36 ("Poly(ε-caprolactone)") ("[Poly(orthoesters)] have therefore been exploited as constant rate drug delivery devices.") ("Poly(anhydrides)"); p.36-41 ("Hydrophobic polymers") ("Poly(ethylene)"); p. 41-44 ("Hydrophilic Polymers") ("Poly(2-hydroxyethyl methacrylate)"); p.44 ("Natural and synthetic biodegradable polymers have been utilized in drug delivery and tissue engineering. Drug delivery systems based on biodegradable polymers facilitate the controlled release of drugs with the concurrent degradation of the polymer.").

Chandrasekaran: p.587 ("The simplest to a bioerodible drug delivery system is to disperse or dissolve the drug in a water-soluble polymer, which will slowly erode in an aqueous medium Another approach involves the synthesis of hydrophobic water-insoluble polymers in which the major fraction of the drug is released by erosion of the polymer matrix . . ."); p.588 ("Hydrophobic polymer solubilization can be achieved as a result of a chemical reaction that takes place at either a pendant group of the polymer or within the polymer backbone. When the reaction is confined to the pendant group, no backbone cleavage takes place, and one of the reaction products is a hydrolytically stable water-soluble polymer. . . . Hydrophobic polymers can also be solubilized by an ionization reaction of pendant carboxyl groups; drug dissolution and release rate kinetics are obtained from partially esterified copolymers derived from ethylene-maleic anhydride or methyl vinyl ester-maleic anhydride.").

Kim: p194-96; Fig.4; 197-201 ("Drug Diffusion through Polymers"); p.202-204 ("Release Rate from Monolithic Devices"); p.204-206 ("Mechanistic Considerations of Drug Diffusion through Polymer Membranes"); p.215-220 ("Hydrophobic Polymers as Drug Carriers") ("Ethylene-Vinyl Acetate Copolymer (EVA)"); p.220-23 ("The synthesis of

biodegradable polymers for controlled drug release is based on different strategies. 1. A degradable polymer medium to which a drug is dispersed. Here drug diffusion through the polymer matrix is influenced by the degradation of the polymeric material. 2. A degradable polymer medium to which a drug is attached through a hydrolytically labile linkage. Drug release is controlled by both hydrolysis of the drug from the polymer and by diffusion of the drug through the polymer matrix."); p.226-28 ("Design of Chemically Bound Polymer-Bioactive Agent (PBA) Systems"); p.228-29 ("Models of Chemically Bound Polymer-Bioactive Agent Systems."); p.229-46 ("Examples of Chemically Bound Polymer-Bioactive Agent Systems").

Dev: Abstract; p. 273 ("The purpose of this study was twofold: first, to test a polymer-coated removable stent system for local delivery of two lipid soluble drugs . . . and second, to compare these two drugs with respect to kinetics of their delivery to the arterial wall with the stent in place and their tissue washout rates after removal of the stent."), ("We used a commercially available biomedical grade polyurethane [as a stent coating]. . . . To study the kinetics of drug delivery, we used two lipid soluble compounds: forskolin and etretinate."), ("Ratio of peak drug levels in the vessel wall to those in the blood was 6,000 for etretinate and 780 for forskolin. . . . Polymer-coated stents could be used for local drug delivery to the vessel wall."); p. 274-75 ("the drug levels [of etretinate] in blood and the distant tissues are extremely low, and the ratio of local to systemic drug levels is very high (~6,000); p. 277 ("This [preferential release of drug into the arterial wall] may reflect slower diffusion of etretinate in the aqueous medium than forskolin or presence of significant tissue binding of etretinate.").

Claim 1 [1G] (cont'd): the device being
flexible in three dimensions by manipulation by
human hands,

Where Found in the Prior References:

Peterson '166: Col. 2:51-54 ("Typical polymeric carriers are polyesters, polyamides, polyurethanes and other condensations polymers . . .").

Schwartz '823: Abstract ("A radially expandable stent . . . the cylindrical body comprising a plurality of metal elements joined to allow flexing of the cylindrical body along the longitudinal axis of the body whereby the stent can conform to a curved body lumen . . ."); col. 1:9-14; col. 1:17-19; col. 1:53-55; col. 2:16-19 ("It is therefore an object of the present invention to provide a stent having longitudinal flexibility which allows it to conform to curves and variation in body lumens."); col. 2:29-40; col. 2:44-49; col. 3:48-57; col. 3:58-64 ("The improvement of the present invention includes applying to the above-mentioned type of stent a flexible or elastomeric polymeric film which extends between the metal elements."); col. 4:20-27 ("The term 'film' or 'flexible film' herein therefore means that, as applied to the metal stent elements in a thin cross section, the film is capable of flexing or stretching to preserve the radial expandability and axial flexibility of the implanted stent."); col. 4:49-5:41 ("It also produces a stent having a flexible film which extends between the metal elements of the stent and which will not significantly affect the ability of the stent to conform to curved body lumens. . . . A suitable

crimping tool . . . may be used to tighten the stent over the balloon. A manual operation of sequentially squeezing the stent over the balloon is also acceptable."); col. 5:65-6:1; col. 6:17-20; col. 6:30-32; col. 6:43-47; col. 6:49-52; col. 6:58-68; col. 8:19-41.

Scott '928: Col. 8:23-60 (disclosing use of EVA).

Tartaglia '113: Abstract; col. 1:15-19 ("Ideally, implantation of such stent is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:57-60 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member."); col. 1:64-67 ("The polymer material can be a thermoplastic or an elastomer, for example, so that the film can stretch or deform radially when the stent structural member is expanded."); col. 2:23-33; col. 2:48-55; col. 5:6-10; col. 6:54-56; col. 7:18-21 ("The apertures also improve the flexibility of the polymeric material, allowing the stent segment to be more easily rolled and uncoiled during expansion of the stent structural member . . ."); col. 10:40-47.

Wolff '208: Col. 2:7-9 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 9:39-42 ("The device is fixed into place either by radial expansion in devices such as shown in Fig. 1 or are deformed by a balloon catheter in the case of devices in accordance with Fig. 2."); col. 10:3-45 ("The stents are arranged on the distal end of the catheter such that the catheter can provide remote, transluminal deployment of the stents, with the metal stent inside the polymeric stent, from an entry point into a selected portion of the body lumen to be treated and also remote actuation of an expansion mechanism from the proximal end of the catheter. The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen."); col. 10:51-57; col. 10:66-11:3 ("The metal stent is crimped onto the balloon and includes an elongated lead extending to the proximal end of the catheter assembly where it includes an enlarged portion to enable an operator to securely grip the lead."); col. 12:1-15.

Berg '354: Page 2:14-15 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen."); p.3:18-22 ("The transluminal delivery can be accomplished by a catheter designed for the delivery of stents and the radial expansion can be accomplished by balloon expansion of the stent, by self-expansion of the stent, or a combination of self-expansion and balloon expansion. Thus the present invention provides a stent which may be delivered and expanded in a selected blood vessel without losing a therapeutically significant amount of a drug applied thereto."); p. 5:28-29.

Buscemi '450: Col. 1:58-60; col. 7:10-20 (" . . . said tubular main body including a slot extending lengthwise through the main body and defined by opposing edges of the main body

wherein the opposing edges must be moved toward each other under compression in order to transport the biodegradable stent through a vessel of a living being . . ."); col. 8:18-24.

Ding '536: Col. 1:48-51 ("One type of self-expanding stent has a flexible tubular body formed of several individual flexible thread elements each of which extends in a helix configuration with the centerline of the body serving as a common axis."); col. 3:5-9; col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 3:56-64 (" . . . the tubular body is formed of a self-expanding open braid of fine, single or polyfilament metal wire which flexes without collapsing, readily axially deforms to an elongate shape for transluminal insertion via a vascular catheter and resiliently expands toward predetermined stable dimensions upon removal in situ.").

Dinh '227: Col. 1:32-35 ("The stent is typically inserted by catheter into a vascular lumen told [sic] expanded into contact with the diseased portion of the arterial wall, thereby providing mechanical support for the lumen."); col. 2:62-66 ("The inclusion of a polymer in intimate contact with a drug on the underlying stent structure allows the drug to be retained on the stent in a resilient matrix during expansion of the stent and also slows the administration of drug following implantation."); col. 3:14-22; col. 6:62-67; col. 7:13-21; col. 8:29-43 ("For example, a deformable metal wire stent such as that disclosed in U.S. Pat. No. 4,886,062 issued to Wiktor could be coated with fibrin as set forth above The stent and fibrin would could then be placed onto the balloon at a distal end of a balloon catheter and delivered by conventional percutaneous means . . . to the site of the restriction or closure to be treated where it would then be expanded into contact with the body lumen by inflating the balloon."); col. 8:49-52 ("A catheter has a balloon upon which a stent has been placed, the stent having a deformable metal portion and a fibrin coating, thereon."); col. 8:64-9:2; col. 9:18-24; col. 9:49-50 ("The resulting fibrin stent includes the stent embedded in a very thin elastic film of fibrin."); col. 9:59-63; col. 12:24-28.

Domb '055: Abstract ("Preferred embodiments include catheters, tubes, and implants that abut tissue following implantation into the body . . ."); col. 4:25-32; col. 5:27-37 ("In a particularly preferred embodiment, polymers incorporating steroids are coated onto devices including tracheal T-tubes, stoma stents, laryngeal/bronchial stents, laryngeal keels, and nasogastric tubes."); col. 5:46-54; col. 5:60-62; col. 7:10-20; col. 7:40-52; col. 9:15-30; col. 9:55-10:2; col. 10:21-52; col. 10:60-11:11.

Fox '096: Col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages.").

Hunter '981: Col. 16:31-56; col. 17:63-18:7 ("[T]he anti-angiogenic compositions of the present invention may be formed as a film. . . . Such films are preferably flexible with a good

tensile strength . . . and has controlled permeability."); col. 22:3-7; col. 22:21-39; col. 22:54-58; col. 23:26-30; col. 60:35-45; Fig. 17E; col. 66:13-22 ("As discussed above, sterile, pliable, stretchable drug-polymer compounds (e.g., films) may be utilized in accordance with the methods described herein in order to isolate normal surrounding tissues from malignant tissue during resection of cancer.").

Kowligi '782: Col. 4:28-37.

Lambert '922: Col. 3:54-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); col. 8:1-6.

Lambert '308: Page 6:21-28 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected.").

Myler '563: Abstract ("When elongated in an axial direction, the stent is reduced in cross-sectional area."); col. 2:13-16 ("The stent is configured to permit radial expansion, such as under the force generated by balloon dilation, and radial contraction in response to axial elongation."); col. 2:22-26; col. 2:27-28; col. 3:13-15; col. 3:33-34; col. 3:44-46; col. 3:48-51 ("Alternatively, tubular stents formed from flexible non-metal materials such as elastomeric polymers or rubber (latex) can also be radially reduced by axial elongation in accordance with the present invention."); col. 3:58-61; col. 4:9-12; col. 4:30-43 ("Suitable envelope materials include elastic materials such as latex and others that can be readily selected by one of skill in the art. . . . In general, biocompatible materials which can tolerate expansion of the stent between the insertion diameter and expanded diameter can be used."); col. 5:1-16; col. 5:50-54; col. 6:18-23; col. 10:12-14 ("The balloon is inflated, thereby expanding the stent radially outwardly until it contacts either a previously dilated, or presently stenosed wall."); col. 11:55-58; col. 11:63-65; col. 12:11-13; col. 12:19-23; col. 12:63-13:1 ("Suitable coating materials include elastic materials such as polyethylene or PET or other materials that can be readily selected by one of skill in the art. In general, any biocompatible material which can tolerate expansion of the stent between the insertion diameter and treatment diameter can be used."); col. 13:61-66; col. 19:18-30; col. 19:65-20:7; col. 20:51-57.

Palmaz '417: Abstract ("A plurality of expandable and deformable intraliminal vascular grafts are expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 1:17-23 ("The invention relates to an expandable intraliminal graft for use within a body passageway or duct and, more particularly, expandable intraliminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease; and a method and apparatus for implanting expandable intraliminal grafts."); col. 3:56-4:7; col. 4:28-37; col. 5:4-5:20 ("The present invention includes: a plurality of expandable and deformable, thin-walled tubular prostheses . . ."); col. 5:41-43; Fig.

10; Fig. 9; col. 6:6-9; col. 6:20-22; col. 6:63-7:2; col. 7:64-8:2; col. 8:36-60; col. 10:6-14; col. 10:55-58 ("Disposed between adjacent tubular members, or adjacent grafts, or prostheses, is at least one connector member to flexibly connect adjacent tubular members, or grafts, or prosthesis."); col. 12:19-21; col. 12:33-38; col. 12:41-63 ("As seen in Fig. 9, because of the disposition of flexible connector members between adjacent tubular members 71, or grafts, or prostheses 70, graft, or prosthesis 70' is able to flexible bend or articulate, with respect to the longitudinal axis of graft, or prosthesis, 70', so as to be able to negotiate the curves or bends found in body passageways. . . . It should be noted that connector members permit the bending, or articulation, of adjacent tubular members in any direction about the longitudinal axis of graft, or prosthesis."); col. 12:64-66; Fig. 10; col. 12:66-13:2; col. 13:22-24; col. 13:31-40; col. 14:17-19; col. 14:27-29; col. 14:41-43; col. 14:48-59; col. 15:18-30; col. 15:33-40; col. 15:61-63; col. 15:67-16:6; col. 16:20-29; col. 16:34-37; col. 16:45-54; col. 16: 59-67.

Aebischer '486: Col. 3:56-63.

Schiraldi '243: Col. 1:8-21 ("The extruded film drug delivery system of the present invention, which has incorporated therein the medicament to be dispensed, is so thin and flexible when wet as to be unobtrusive to the patient after it has been properly positioned and placed in the mouth."); col. 2:30-51.

Valentini '029: Col. 1:56-2:4; col. 2:29-41 ("The devices can be formed from various polymeric materials, such as acrylic copolymers, polyvinylidene fluoride or polyurethane isocyanate, adapted to receive the ends of the severed or otherwise damaged nerve."); col. 3:62-67 ("The sheet is then wrapped around the nerve segments and the resulting tube is closed by further sutures, adhesives or friction."); col. 4:46-59 (disclosing use of flexible polymeric materials).

Wood '066: Abstract; col. 2:56-3:17; col. 7:51-65; col. 17:19-22; col. 17:30-34 (" . . . to give a flexible, elastomeric, white cryogel membrane . . ."); col. 18:1-4; col. 18:13-16; col. 18:26-30.

Strecker '746: Abstract ("An endoprosthesis in the form of an elongated hollow structure . . . once correctly positioned will expand from an initial state with a narrow lumen into a state with a lumen that is as wide as its placement will allow. It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen."); col. 1:12-22 ("Once correctly positioned it will expand from an initial state with a narrow lumen into a state with a lumen that is as wide as its placement will allow. . . . The lumens can be expanded by mechanically stretching them with a known balloon catheter. They can also be compressed prior to implantation and stretch out on their own subject to the resilience introduced by the compression."); col. 1:63-2:2; col. 2:21-32; col. 2:33-38; col. 2:65-3:4; col. 6:30-32; col. 7:16-35; col. 8:19-10:19.

Lambert '246: Col. 3:55-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected.)").

Bellamkonda '029: Col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 4:48-57; col. 10:32-40; col. 11:33-40.

Dayton '382: Abstract ("The device comprises a stent which is formed from metal or polymers into a predetermined shape which includes a plurality of holes . . . to provide a desired bending modulus."); col. 3:62-4:12; col. 4:42-50; col. 4:54-5:3; col. 8:42-59.

Burt '036: p.14:9-27; p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size.").

Goldin '568: Col. 1:55-62 ("Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:8-12; col. 2:24-29 ("Microporous membranes for release of proteins by controlled diffusion have been fabricated from ethylene vinyl acetate (EVA) . . .").

Palmaz '665: Abstract ("An expandable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 1:11-17; col. 3:3-7; col. 3:33-39; col. 4:1-6; col. 4:33-36; col. 6:4-11; col. 7:20-25.

Palmaz '762: Abstract ("An expandable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 3: 45-51 ("...upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular shaped member may be expanded and deformed to expand the lumen of the body passageway."); col. 4: 14-19; col. 4: 43-46; col. 5: 43-45; col. 6: 18-24; col. 8: 7-21.

Palmaz '337: Abstract ("An expandable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 3: 37-44 ("... and the tubular shaped member having a second, expanded diameter, upon the application from the interior of the tubular shaped member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular shaped member, whereby the tubular shaped member may be expanded to expand the lumen of the body passageway."); col. 3:60-4:2 ("The method of the present invention comprises the steps of: ... and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded, ..."); col. 8: 17-22.

Zaffaroni '254: Col. 7: 5-8 ("Device 10 is capable of being substantially straightened by passing through a hollow instrument for positioning it in the uterus 25.").

Aebischer: p. 284 (disclosing manipulation of polymer tube to allow entry of nerve stumps).

Dev: p. 273 ("We used a commercially available biomedical grade polyurethane . . . Tecoflex is a biocompatible, flexible, and an elastic membrane-forming polymer.").

Claim 1 [1H] (cont'd): the device being capable of substantially restricting the through passage of at least one type of macromolecule therethrough.

Where Found in the Prior References:

Schwartz '823: Abstract; col. 2:29-40; col. 2:49-53; col. 3:58-61 ("The improvement of the present invention includes applying to the above-mentioned type of stent a flexible or elastomeric polymeric film which extends between the metal elements."); col. 3:64-4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof."); col. 6:17-20; col. 7:25-8:11.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); Fig. 3; col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-33; col. 5:34-6:29; col. 6:37-41; col. 6:41-45 ("Modifications of the polymer coating include a ring that encompasses the proximal portion of the stent, single or multiple strips that cover a portion of the stent, or a polymer coating with perforations."); col. 8:23-25 ("Ethylene vinyl acetate copolymer (EVA) (Catalog #34,691-8) was obtained from Aldrich Chemical Company, Inc. (Milwaukee, Wis.); col. 10:24-33; col. 12:1-6; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial

lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow Controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Col. 1:7-10 ("This invention relates generally to expandable intraliminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 1:64-2:2 ("The polymer material can be a thermoplastic or an elastomer, for example, so that the film can stretch or deform radially when the stent structural member is expanded. The film of polymer material can be formed as a solid sheet, or can incorporate holes of various sizes and shapes to promote rapid endothelialization."); col. 4:15-24; col. 4:25-46; col. 4:47-5:3; col. 5:4-9; col. 5:49- 6:25 ("The polymeric material is preferably selected from thermoplastic and elastomeric polymers. . . . In another currently preferred embodiment, the polymeric material can be ethylene vinyl acetate (EVA) . . ."); col. 6:26-65; col. 7:23-42; col. 7:63-65; col. 8:12-57; col. 9:5-12; col. 10:12-30.

Wolff '208: Col. 2:7-16 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:28-30 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 6:59-62 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously. The polymer may be biostable or bioabsorbable. If biostable, the drug would diffuse out of the polymer."); col. 6:64-67; col. 7:59-61; col. 9:23-33 ("That layer may be a simple barrier which limits diffusion of drugs in the polymer. In that event, the smaller molecules could elute out immediately, while larger compounds would not elute until later when the layer has biodegraded."); col. 12:37-40 ("8. The device of claim 1 also comprising a barrier coating of polymeric material on the drug-containing filament to limit the rate of drug elution.").

Berg '354: Page 2:43-54 ("Viewed from a further aspect the invention provides the use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug-eluting surface coating."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution

which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:29-31 ("Also, stents made with biostable or bioabsorbable polymers such as poly(ethylene terephthalate), polyacetal, poly(lactic acid), poly(ethylene oxide)/poly(butylene terephthalate) copolymer could be used in the present invention. "); Table 1; p. 4:5-24; p. 6:6-11; p. 6:15; p. 6:24-35; p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Abstract ("A stent made of biodegradable material includes a drug that is released at a rate controlled by the rate of degradation of the biodegradable material."); col. 2:16-17; col. 4:1-5 ("In one embodiment, the main body includes a film that is preferable combined with the plurality of fibers disposed around the main body. The film combined with the plurality of fibers defines the outer surface of the main body."); col. 4:15-16 ("Preferable, the main body of the stent includes a film covering the inner surface."); col. 4:19-22.

Ding '536: Abstract ("The coating includes a relatively thin layer of biostable elastomeric material containing an amount of biologically active material, particularly heparin, dispersed in the coating in combination with a non-thrombogenic surface."); col. 1:24-29 ("The present invention relates generally to providing biostable elastomeric coatings on the surfaces of implants which incorporate biologically active species having controlled release characteristics in the coating particularly to providing a non-thrombogenic surface during and after timed release of the biologically active species."); col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 5:10-56 ("Polymers generally suitable for the undercoats or underlayers include silicones (e.g., polysiloxanes and substituted polysiloxanes), polyurethanes, thermoplastic elastomers in general, ethylene vinyl acetate copolymers, polyolefin elastomers, polyamide elastomers, and EPDM rubbers. The above-referenced materials are considered hydrophobic with respect to the contemplated environment of the invention."); col. 12:62-13:2; col. 13:13-26; col. 13:37-40; col. 14:5-17; col. 14:22-34.

Dinh '227: Col. 2:51-54 ("To accomplish this while not affecting the strength of the overall fibrin stent structure, a first layer is applied to a stent body, the first layer incorporating a polymer and the therapeutic substance."); col. 2:62-66 ("The inclusion of a polymer in intimate contact with a drug on the underlying stent structure allows the drug to be retained on the stent in a resilient matrix during expansion of the stent and also slows the administration of drug following implantation."); col. 3:10-14; col. 3:25-38; col. 5:3-7; col. 5:44-55; col. 5:56-57; col. 6:13-19 ("In U.S. Pat. No. 4,548,736 issued to Muller et al., a dense fibrin composition is disclosed which can be a bioabsorbable matrix for delivery of drugs to a patient. Such a fibrin composition can also be used in the present invention by incorporating a drug or other therapeutic substance useful in diagnosis or treatment of body lumens to the fibrin provided on the stent."); 6:50-56 ("Alternatively . . . a dense fibrin composition suitable for drug delivery can be made without the use of microcapsules by adding the drug directly to the fibrin followed by

compression of the fibrin into a sufficiently dense matrix that a desired elution rate for the drug is achieved."); col. 6:62-67; col. 7:10-13; col. 7:56-64 ("In another embodiment of the invention, the coating of polymer and drug on the stent is achieved by forming a first fibrin layer on the stent body which incorporates the therapeutic substance and then applying a second layer of fibrin."); col. 8:52-60 ("Fig. 2 shows an alternative stent in which a fibrin film has been affixed to the underlying metallic framework by affixing it to the stent . . ."); col. 8:64-9:3; col. 12:24-28; col. 12:38-50.

Domb '055: Abstract ("Devices are provided having a polymer coating incorporating compounds inhibiting inflammation and infection, along with subsequent tissue growth onto and around the device. . . . Preferred polymeric coating are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); col. 1:12-15 ("This invention relates to invasive medical devices for delayed/sustained release of pharmaceutical compositions from a polymer that is coated or incorporated into the devices."); col. 3:54-57 ("In the preferred embodiments, these have utilized bioerodible polymers as the matrix for the drug to be released, usually as a function of diffusion and erosion of the polymer."); col. 4:22-36; col. 5:24-37; col. 5:41-45; col. 5:48-6:1; col. 6:24-26 ("Examples of suitable polymers include ethylene vinyl acetate, polyurethane, silicones, hydrogels, polyurethane, and polyvinyl chloride."); col. 7:10-20; col. 7:40-52; col. 9:15-30; col. 9:55-10:2; col. 10:21-52; col. 10:60-11:11; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 11:36-38 ("The medical device of claim 1, wherein the polymer is selected from the group consisting of polyurethane, ethylene vinyl acetate, silicones, hydrogels, and polyvinyl chloride."); col. 11:39-44; col. 12:11-22; col. 12:23-25; col. 12:26-31; col. 12:32-42.

Fox '096: Abstract ("A method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers, and antimicrobial agents . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 2:48-65; col. 3:55-67 ("The polymeric coating agent component of the coating vehicle of the present invention is selected from the group consisting of biomedical polyurethanes, biomedical silicones, biodegradable polymers and combinations thereof."); col. 19:11-16; col. 31:62-64.

Hunter '981: Col. 1:12-17; col. 3:42-45 ("Within one aspect of the present invention, compositions are provided (anti-angiogenic compositions) comprising (a) an anti-angiogenic

factor and (b) a polymeric carrier."); col. 3:53-61; col. 12:23-25 ("As noted above, the present invention provides compositions comprising an anti-angiogenic factor, and a polymeric carrier."); col. 16:31-56; col. 17:63-18:7 ("[T]he anti-angiogenic compositions of the present invention may be formed as a film. . . . Such films are preferably flexible with a good tensile strength . . . and has controlled permeability."); col. 22:3-7; col. 22:54-58; col. 47:58-49:7; col. 52:4-8; col. 69:19-62; col. 84:62-86:24; 86:56-59; col. 87:11-22; col. 88:19-26.

Kowligi '782: Abstract ("The elastomeric coating is made of polyurethane or another biocompatible non-porous elastomers and precludes tissue ingrowth into the outer cylindrical wall, minimizes suture hold bleeding, and increases suture retention strength, while reducing the incidence of serous weepage."); col. 1:18-26; col. 2:15-20; col. 2:38-47; col. 2:53-59; col. 3:27-37; Fig. 1; Fig. 2; Fig. 3; col. 2:60-67 ("PTFE tube 32 includes an inner cylindrical wall and an opposing outer cylindrical wall. As shown in Fig. 2, outer cylindrical wall 36 is coated entirely around its circumference by a uniformly thick coating of a biocompatible elastomer."); col. 3:27-38; col. 4:16-27 ("In regard to elastomeric coating 38 shown in Fig. 2, such elastomeric coating is selected to be a biocompatible elastomers and may be selected from the group consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 4:37-39 ("The elastomeric coating should also be sufficiently non-porous to preclude serous weepage and inhibit tissue ingrowth therethrough."); col. 5:4-7; col. 7:49-8:9; col. 8:38-44; col. 9:65-10:6; col. 10:18-24; col. 10:33-42; col. 10:43-50; col. 10:51-59; col. 10:60-67.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 2:16-35; col. 2:40-50; col. 3:8-12; col. 3:29-32; col. 3:33-49; col. 3:55-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); col. 7:29-32; col. 7:38-41; col. 10:57-64; col. 11:49-51; col. 11:65-12:13; col. 12:43-64; col. 13:13-19.

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p. 3:10-31 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); p. 4:2-12; p. 6:21-28 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be

subjected."); claim 1:1-14; claim 8:1-5; claim 10:1-3; claim 11:1-13; claim 22; claim 23:1-14; claim 19:4-31.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8.

Myler '563: Col. 2:10-13; col. 3:13-15; col. 3:52-54; col. 4:30-43 ("In a preferred embodiment, the interior and exterior walls of stent 10 are enclosed in a thin polymeric envelope. . . . Suitable envelope materials include elastic materials such as latex and others that can be readily selected by one of skill in the art."); col. 5:1-16; col. 5:39-41 ("For the above reasons, even the expanded pores for drug delivery should be small enough to maximize or prevent cell penetration, but large enough for drug delivery."); col. 12:11-13; col. 12:19-23; col. 12:28-33 ("Suitable materials include elastomeric polymers or natural rubber (latex). . . . Polymeric stents can be provided with relatively fluid impenetrable walls, or porous walls such as to allow drug delivery, as will be apparent to one of skill in the art."); col. 12:63-65 ("Suitable coating materials include elastic materials such as polyethylene or PET or other materials that can be readily selected by one of skill in the art."); col. 18:51-19:9; col. 19:18-30; col. 19:31-32; col. 19:61-63; col. 20:33-49; col. 20:51-57.

Palmaz '417: Col. 6:66-68; col. 11:3-14 ("Examples of a suitable biologically compatible coating would be porous polyurethane, Teflon™ or other conventional biologically inert plastic materials."); col. 11:26-31 ("Examples of biologically compatible coatings would include coatings made of absorbable polymers such as those used to manufacture absorbable sutures. Such absorbable polymers include polyglycoides, polyacoides, and copolymers thereof.");

Tice '330: Col. 3:20-33 ("Suitable wall forming materials include polystyrene, ethylcellulose, cellulose acetate, hydroxyl propylmethylcellulose phthalate, cellulose acetate, dibutylaminohydroxypropyl ether, polyvinylbutyral, polyvinyl formal, poly(meth)acrylic acid ester, polyvinylacetal-diethylamino acetate, 2-methyl-5-vinyl pyridine methacrylate-methacrylic acid copolymer, polycarbonate, polyesters, polypropylene, vinylchloride-vinylacetate copolymer, polysaccharides, glycerol distearate, and the like. A preferred group of polymeric wall forming materials includes those which are biodegradable such as aliphatic polyesters including polylactide, polyglycolide, polycaprolactone and copolymers thereof."); col. 8:38-51.

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); col. 3:7-18; col. 3:56-63; col. 4:31-34 ("The outer membrane surface is nonporous, while porous inner membrane surface allows for the diffusion therethrough of active factor 26."); col. 5:18-28 ("In a preferred embodiment of the invention, the outer surface of the membrane is impermeable to solutes of any size, while the inner membrane surface contains pores [that] enable the active factors to diffuse out of the membrane and into the lumen of the channel."); col. 6:17-22 ("The layering procedure allows deposition of an impermeable coat on the outer surface of the device, insuring that the active factors incorporated into the membrane

walls will be inhibited from diffusing through the external surface, and will diffuse only through the inner membrane surface into the lumen of the channel."); 6:54-61; col. 9:18-10:3.

Folkman '560: col. 2:43-68 ("A biocompatible plastically deformable polymer matrix . . . substantially impermeable to a macromolecule"); col. 3:18-23 ("The polymer matrixes, which are suitably used in the present invention, are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:36-51 ("Typical polymeric material suitable for forming the matrix . . . include . . . alkylene-vinyl acetate copolymers . . . crosslinked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:52-4:26 ("In the presently preferred embodiment the polymeric materials useful for forming the matrix are the ethylene vinyl ester copolymers of the general formula . . ."); col. 11:56-12:20.

Cohen '496: Col. 3:26-45 ("The polymer matrices . . . are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:65-4:39 ("In a presently preferred embodiment, the polymeric materials useful for forming the matrix are the ethylenevinyl ester copolymers of the general formula . . ."); col. 9:40-10:17; col. 10:18-32.

Schiraldi '243: Col. 1:8-21 ("The extruded film drug delivery system of the present invention, which has incorporated therein the medicament to be dispensed, is so thin and flexible when wet as to be unobtrusive to the patient after it has been properly positioned and placed in the mouth."); col. 1:58-60; col. 2:30-51; col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 9:36-55; col. 10:12-18.

Valentini '029: Abstract ("Medical devices employing semipermeable materials, such as acrylic copolymers, polyurethane isocyanate, and other biocompatible semipermeable polymers, are disclosed for use as guidance channels in regenerating nerves. . . . The guidance materials are chosen such that they are capable of allowing the diffusion of nutrients and other metabolites to the regenerating nerve site while excluding fibroblasts and other scar-forming cells."); col. 2:29-57 ("It has been discovered that the repair of severed or avulsed nerves can be greatly enhanced by the use of selectively permeable polymeric materials as nerve guidance channels. . . . The devices can be formed from various polymeric materials, such as acrylic copolymers, polyvinylidene fluoride or polyurethane isocyanate Preferable, the materials allow passage therethrough of solutes having a molecular weight of about 100,000 daltons or less. . . . The nerve guidance channels of the present invention are also preferably designed to retain nerve

growth factors secreted at the anastomatic site or seeded therein, as well as retain any luminal matrix material placed inside the guidance channels."); col. 2:58-3:14; col. 4:46-59; col. 5:13-32 ("The success rate and quality of peripheral nerve regeneration was dramatically enhanced through the use of a semipermeable material."); col. 5:42-6:12 ("The permselective characteristics of the inner membrane allow the exchange of nutrients, while concentrating growth factors released by the nerve and excluding scar-forming cells."); col. 6:14-24; col. 6:31-42.

Greco '135: Col. 3:48-4:1 ("These devices will consist of organic polymers and/or metallic materials including: . . . polyethylene . . . elastomeric organosilicon polymers, such as polysiloxanes, e.g. Silastic ®").

Aebischer '627: Col. 3:57-4:3 ("The polymeric insert includes pores having a molecular weight exclusion of from about 1 kD to about 1,000 kD, but preferably from about 25kD to about 100 kD."); col. 4:11-27 ("The terms 'semipermeable' is used herein to describe biocompatible membranes that allow the diffusion therethrough of molecules having a relatively low molecular weight, while excluding the passage of those having a relatively high molecular weight. . . . The semipermeable membrane can be made of various polymeric compositions such as polyvinylchloride, polyacrylonitrile, polyvinylidene fluoride, polystyrene, polymethylmethacrylate, polysulfone, and acrylic copolymers."); col. 7:57-8:14 ("In this embodiment, a semi-permeable membrane functions as a protective cell culture device for the neurotransmitter-secreting cells. The pores of the membrane should be large enough to enable the exchange of metabolites with body fluids, and to permit the diffusion therethrough of neurotransmitter produced by the cells therein, but are small enough to bar the passage therethrough of larger elements deleterious to the cells."); col. 13:31-48; col. 13:66-68; col. 14:1-2; col. 14:22-28; col. 14:54-56.

Wood '066: Abstract ("A controlled-release bandage containing therapeutic agents in a poly(vinyl alcohol) cryogel is disclosed. The bandage may include . . . hydrophobic particles to further insure controlled and constant release of therapeutic agents."); col. 2:56-66; col. 23:4-11.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:63-2:2; col. 2:12-15 ("The present invention on the other hand exploits a wrapping material that plastically deforms as it expands . . ."); col. 2:21-38; col. 2:59-64; col. 3:7-16; col. 3:27-33 ("The lining can to advantage be made of polymers or compounds thereof."); col. 3:51-62; col. 3:51-62; col. 5:49-54 ("The thread itself in an endoprosthesis of the type illustrated in Fig. 3 can also be wrapped in a coat of medicated and biodegradable wrapping material. . . . The prosthesis can of course alternatively be enclosed in a flexible-tubular coat."); col. 6:50-55; col. 6:59-62; col. 7:16-35; col. 8:4-8; col. 8:19-10:19.

Lambert '246: Abstract ("Thus, a polyurethane coating is applied to a prosthetic article, the coating then swelled . . . so that substantial quantities of biologically active compounds can be incorporated within the interstices of the polymer."); col. 2:15-34; col. 2:40-49; col. 2:53-65;

col. 3:55-4:35 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility to as to enable the application of a stable coating onto substrate (i.e. the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected)."); col. 10:45-67; col. 11:34-59; col. 12:15-41.

Bellamkonda '029: Abstract ("A nerve guidance channel for use in regenerating severed nerve is prepared containing a tubular semi-permeable membrane having openings adapted to receive the ends of a severed nerve, and an inner lumen containing the matrix having an adhesive peptide fragment through which the nerve can regenerate."); col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 4:9-14; col. 4:21-39 ("Any suitable hydrogel may be used as the substrate for the bioartificial extracellular matrices of this invention."); col. 4:48-57; col. 5:10-14 ("Several physical properties of the hydrogel matrices of this invention are dependent on gel concentration. Increase in gel concentration may change the gel pore radius, morphology, or its permeability to different molecular weight proteins."); col. 7:13-25; col. 10:28-40 ("Permeable channels with a molecular weight cut-off of 50,000 daltons allowed regeneration of nerves in a mouse sciatic nerve model."); col. 10:41-63; col. 10:64-11:13; col. 12:13-16 ("Preferably the permeable membrane is fabricated to be impermeable to some of these substances so that they are retained in the proximity of the regenerating nerve ends."); col. 12:17-25 ("Briefly, various polymers and polymer blends can be used to manufacture the nerve guidance channel."); col. 12:42-49; col. 19:7-16; col. 23:54-24:55.

Dayton '382: Abstract ("The device comprises a stent which is formed from metal or polymers into a predetermined shape which includes a plurality of holes . . . to provide a desired bending modulus. The stent is then coated with a polymer . . . which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids, with the equilibrium being controlled by charge distribution, concentration and molecular weight of the bioactive substance in relation to the pore size of the polymeric carrier for controlled prolonged release of said bioactive substance."); col. 3:62-4:4:17 ("Among these polymers are polymers having a microporous structure, such as . . . biodegradable polylactic acid polymers, polyglycolic acid polymers . . ."); col. 4:24-33 ("A bioactive substance is preferably admixed in the polymer for elution from the microporous structure of the stent or coating on the stent after implantation. The rate of elution of the bioactive substance is controlled by selecting a pore size for microporous structure . . ."); col. 4: 42-50; col. 4:54-5:3; col. 6:64-7:7 ("The polymer should have a microporous structure with a predetermined pore size."); col. 8:19-33; col. 8:42-59; col. 8:66-9:5; col. 10:1-2.

Burt '036: p. 4:19-33 ("Similarly a wide variety of polymeric carriers may be utilized, representative examples of which include poly(ethylene-vinyl acetate) . . . and copolymers of polylactic acid and polycaprolactone."); p.10:17-25; p.14:9-27 ("As noted above, anti-angiogenic compositions of the present invention comprise an anti-angiogenic factor and a polymeric carrier. In addition to the wide array of anti-angiogenic factors and other compounds discussed

above, anti-angiogenic compositions of the present invention may include a wide variety of polymeric carriers, including for example both biodegradable and non-biodegradable compositions."); p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size."); p.51:1-52:35.

Goldin '568: Col. 1:43-62 ("Release by controlled diffusion may be accomplished by means of containment of the therapeutic agent within a substrate whose small pore size and/or tortuosity of diffusion path thereof limits the diffusion of said agent through the substrate. . . . The therapeutic agent can be incorporated within the diffusion-limiting substrate Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:24-29 ("Microporous membranes for release of proteins by controlled diffusion have been fabricated from ethylene vinyl acetate (EVA), and said membranes have been used in vivo in a manner which demonstrates their therapeutic potential."); col. 5:28-34 (" . . . underlayment material of controlled pore size can be created and used to fabricate a device of optimal porosity . . . and accessibility of the releasable macromolecule to biological material at or beyond the membrane's external surface . . ."); Fig. 1A; col. 11:58-12:14; col. 13:53-65; col. 14:1-28; col. 14:66-15:67; col. 31:57-32:7 ("The device of claim 1 wherein said microporous underlayment comprises a polymer."); col. 32:16-22.

Palmaz '665: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3:47-51 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5: 30-32 ("FIGS. 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon."); Figures 5 and 6.

Palmaz '337: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3:52-56 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5: 19-21; Figures 5 and 6; col. 8: 28-32; col. 9: 24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '762: Col. 10:28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials."); col.3:65-4:2 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 9: 20-25; col. 10: 28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular

shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Zaffaroni '254: Abstract ("The wall is formed in at least a part of a microporous material..."); col. 1: 19-23 ("The wall of the device is comprised in at least a part of a microporous material..."); col. 3: 5-10; col. 3: 48-53; col. 4: 47-54 ("Wall 11 is formed of a microporous material the micropores 15 of which contain a drug release rate controlling medium, not shown, permeable to the passage of drug, as by diffusion, or by convection, or by a concurrent operation of both, but the rate of passage of the drug through the medium in the micropores is lower than the rate of passage of drug through the solid drug carrier."); col. 5: 3-11.

Aebischer: p. 283 (disclosing impermeable polymer layer that restricts passage of treating material).

Dev: p. 273 ("We used a commercially available biomedical grade polyurethane Tecoflex is a biocompatible, flexible, and an elastic membrane-forming polymer.").

Claim 2 [2A]: The device of claim 1 wherein the at least one treating material is selected from the group consisting of a growth factor, extracellular matrix components, morphogenetic molecules, nerve growth factors, connective tissue growth factors, antibiotics, vitamins, cofactors, a glycosaminoglycan, proteins, a bioactive ion, nuclear or ionic radiation, radiofrequency, molecule produced by fractured tissue, a pharmaceutical, a hormone, and living cells.

Where Found in the Prior References:

Peterson '166: Col. 7:63-8:24 ("A class of bioactive compounds particularly useful in this invention are progestins. The time release chemical delivery system is thus useful in animals, including humans, as a contraceptive delivery system. One particular progestin useful in [sic] norethindrone which has the following formula.").

Schwartz '823: Col. 2:8-16; col. 2:59-68; col. 3:64-4:7; col. 7:4-14 ("By 'therapeutic substance' we mean to include drugs such as those described WO 91/12779 'Intraluminal Drug Eluting Prosthesis' which is incorporated herein by reference. In that application, it is suggested that antiplatelet agents, anticoagulant agents, antimetabolic agents and other drugs could be supplied in polymeric stents to reduce the incidence of restenosis. We also mean to include

within the scope of 'therapeutic substance' any other material useful in diagnosis and treatment such as radio-opaque substances.").

Scott '928: Col. 5:34-63 ("By 'drug' is meant any compound which has a desired pharmacologic effect. Naturally, the drug is compatible with the polymer and can be tolerated in a subject. For example, the drug can be an anticoagulant, e.g., D-Phe-Pro-Arg chloromethyl ketone, and RGD peptide containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, aspirin, prostaglandin inhibitors, platelet inhibitors, or tick anti-platelet peptide. The drug could also be a promoter of vascular cell growth, e.g., a growth factor inhibitor, growth factor receptor agonist, transcriptional activator, or translational promoter. Alternatively, the drug can be an inhibitor of vascular cell growth, e.g., a growth factor inhibitor, growth factor receptor antagonist, transcriptional repressor, translational repressor, antisense DNA, antisense RNA, replication inhibitor, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin, bifunctional molecules consisting of an antibody and a cytotoxin. In addition, the drug could be a cholesterol-lowering agent, a vasodilating agent, and agents which interfere with endogenous vasoactive mechanisms. While the drug utilized in the specific example set forth herein is D-Phe-Pro-Arg chloromethyl ketone, these other compounds can be added to the polymer using very similar methods and routinely tested as set forth in the specification. Any modifications to the system necessary for a particular drug can routinely be made by one skilled in the art."); col. 6:35-36 ("Finally, cultured or autologous cells can be used to line the sheath to achieve endothelialization."); col. 7:60-68; col. 10:34-44 ("2. The sheath of claim 1, wherein the drug is an anticoagulant. 3. The sheath of claim 2, wherein the anticoagulant is D-Phe-Pro-Arg chlormethyl ketone. 4. The sheath of claim 2, wherein the anticoagulant is selected from the group consisting of an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, aspirin, prostaglandin inhibitors, platelet inhibitors and tick anti-platelet peptides."); col. 10:48-54 ("6. The sheath of claim 1, wherein the drug is a promoter of vascular cell growth. 7. The sheath of claim 6, wherein the promoter of vascular cell growth is selected from the group consisting of a growth factor inhibitor, growth factor receptor agonist, transcriptional activator, translational promoter."); col. 10:58-68 ("9. The sheath of claim 1, wherein the drug is an inhibitor of vascular cell growth. 10. The sheath of claim 9, wherein the inhibitor of vascular cell growth is selected from the group consisting of a growth factor inhibitor, growth factor receptor antagonist, transcriptional repressor, translational repressor, antisense DNA, antisense RNA, replication inhibitor, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin, bifunctional molecules consisting of an antibody and a cytotoxin."); col. 11:4-7 ("12. The sheath of claim 1, wherein the drug is selected from the group consisting of a cholesterol-lowering agent, a vasodilating agent, and agents which interfere with endogenous vasoactive mechanisms."); col. 11:22-23 ("18. The sheath of claim 1, wherein the sheath is comprised of at least two different drugs."); col. 12:7-8 ("22. The sheath of claim 1, further comprising cultured or autologous cells which line the sheath.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated

with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Col. 1:7-10; col. 1:25-38; col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 1:50-56 ("The stent can be used in coronary arteries or any other part of the vasculature or other body lumen where mechanical opening force is necessary or desirable to keep the vessel open or to maintain the stent flush against the lumen wall, and where an anti-restenosis, anti-proliferative or other types of therapeutic drug or agent is to be simultaneously positioned and diffused."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 5:4-9; col. 5:64-6:25 ("The polymeric material is preferably bioabsorbable, and is preferably loaded or coated with a therapeutic agent or drug including, but not limited to, antiplatelets, antithrombins, cytostatic and antiproliferative agents The therapeutic agent or drug is preferably selected from the group of therapeutic agents or drugs consisting of sodium heparin, low molecular weight heparin, hirudin, argatroban, forskolin, vapiprost, prostacyclin and prostacyclin analogues, dextran, D-phe-pro-arg-chloromethylketone, dipyridamole, glycoprotein IIb/IIIa platelet membrane receptor antibody, recombinant hirudin, thrombin inhibitor, angiopeptin, angiotensin converting enzyme inhibitors, . . . calcium channel blockers, colchicine, fibroblast growth factor antagonists, fish oil, omega 3-fatty acid, histamine antagonists, HMG-CoA reductase inhibitor, methotrexate, monoclonal antibodies, nitroprusside, phosphodiesterase inhibitors, prostaglandin inhibitor, seramin, serotonin blockers, steroids, thioprotease inhibitors, triazolpyrimidine and other PDGF antagonists, alpha-interferon and genetically engineered epithelial cells, and combinations thereof."); col. 6:2-25; col. 9:3-5; col. 10:12-30; col. 11:4-24.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:63-2:6 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery. . . . Alternatively, the prostheses may be biostable in which case the drug is diffused out from the biostable materials in which it is incorporated."); col. 2:12:-14 ("In all cases, the prostheses of the invention require the presence of an elutable drug compounded to the prosthesis itself. With conventional metal stents, the invention requires a drug-carrying coating overlying at least a portion of the metal."); col. 2:17-24 ("The drugs in the prosthesis may be of any type which would be useful in treating the lumen. . . . Platelet aggregation and adhesion can be controlled with antiplatelets and anticoagulents. Growth factor and receptor blockers and antagonists may be used to limit the normal repair response."); col. 5:23-24 ("Antiplatelet drugs include such as aspirin and dipyridamole."); col. 5:40-41 ("Anticoagulant drugs include Haprain, Coumadin, Protamine, and Hirudin."); col. 5:65-67 ("Anti-replicate drugs include among others:

Methotrexate, Colchicine, Azathioprine, Vincristine, VinBlastine, Fluorouracil, Adriamycin, and Mutamycin."); col. 6:11-14 ("Anti-inflammatory drugs such as glucocorticoids (e.g., dexamethasone, betamethasone) can also be useful to locally suppress inflammation caused by injury to luminal tissue during angioplasty."); col. 9:56-59 ("Elution of the anti-replicates along or in conjunction with the initial elution of anticoagulants can also limit the extent of the restenosis which occurs in the natural healing process."); col. 12:39-51.

Berg '354: Page 2:31-33 ("In the latter two, it is suggested that antiplatelet agents, anticoagulant agents, antimicrobial agents, antimetabolic agents and other drugs could be supplied in stents to reduce the incidence of restenosis."); p. 3:9-13 ("By this method, drugs such as glucocorticoids (e.g. dexamethasone, betamethasone), heparin, hirudin, tocopherol, angiopeptin, aspirin, ACE inhibitors, growth factors, oligonucleotides, and more generally, antiplatelet agents, antimitotic agents, antioxidants, antimetabolite agents, and anti-inflammatory agents can be applied to a stent, retained on a stent during expansion of the stent and elute the drug at a controlled rate."); Table 1; p. 4:31-40; p. 6:40-42.

Buscemi '450: Col. 2:3-6 ("The Goldberg et al patent application describes a method for incorporating radiopaque materials such as barium sulfate into the polymer in amounts ranging from 5-30%. "); col. 2:24-25; col. 2:49-52 ("Also desired are stents which can deliver drugs or biologically active agents at a controlled rate to blood passing through the vessel lumen as well as to the vessel wall."); col. 6:11-28 ("The drugs include but are not limited to drugs that inhibit or control the formation of thrombus or thrombolytics such as heparin or heparin fragments, aspirin, coumadin, tissue plasminogen activator (TPA), urokinase, hirudin, and streptokinase, antiproliferatives (methotrexate, cisplatin, Fluorouracil, Adriamycin, and the like), antioxidants (ascorbic acid, carotene, B, vitamin E, and the like), antimetabolites, thromboxane inhibitors, non-steroidal and steroidal anti-inflammatory drugs, Beta and Calcium channel blockers, genetic materials including DNA and RNA fragments, and complete expression genes, carbohydrates, and proteins including but not limited to antibodies (monoclonal and polyclonal) lymphokines and growth factors, prostaglandins, and leukotrienes.").

Ding '536: Col. 5:60-6:6 ("While heparin is preferred as the incorporated active material, agents possibly suitable for incorporation include antithrombotics, anticoagulants, antibiotics, antiplatelet agents, thrombolytics, antiproliferatives, steroidal and non-steroidal antiinflammatories, agents that inhibit hyperplasia and in particular restenosis, smooth muscle cell inhibitors, growth factors, growth factor inhibitors, cell adhesion inhibitors, cell adhesion promoters and drugs that may enhance the formation of healthy neointimal tissue, including endothelial cell regeneration."); col. 7:24-28; col. 13:27-28.

Dinh '227: Col. 3:14-22 ("By this method, drugs such as glucocorticoids . . . heparin, hirudin, tocopherol, angiopeptin, aspirin, ACE inhibitors, growth factors, oligonucleotides, and, more generally, antiplatelet agents, anticoagulant agents, antimitotic agents, antioxidants, antimetabolite agents, and anti-inflammatory agents can be applied to a stent, retained on a stent during expansion of the stent and elute the drug at a controlled rate."); col. 6:26-32; col. 7:13-21; col. 7:30-44; col. 12:54-60.

Domb '055: Abstract ("... localized chronic infection/inflammation of the tissues surrounding the implant may be decreased by sustained release of antibiotics, antifungals, antivirals, anti-inflammatories, and other compounds, such as anticoagulants and anesthetics."); col. 4:25-32; col. 5:27-33; col. 5:34-37 ("In a particularly preferred embodiment, polymers incorporating steroids are coated onto devices . . ."); col. 5:41-45; col. 5:49-54 ("Scarring and stenosis can be decreased or avoided by using long-term silicone-made sinus ventilation tubes incorporating polymers for sustained release of corticosteroids and antibiotics . . ."); col. 5:55-6:1; col. 6:3-7; col. 6:46-7:3 ("Anti-inflammatories that can be incorporated into the polymeric coatings include steroids and non-steroidal anti-inflammatories. For example, corticosteroids can be dexamethason, hydrocortisone, triamcinolone, methylprednisolone or analogs thereof. Non-steroidal antiinflammatories include compounds such as cyclosporine, ibuprofen, and naproxen. The anti-infectives include antibiotics, antifungals, and antivirals. Exemplary antibiotics include penicillins, cephalosporins, clindamycin, aminoglycosides, tetracyclines and others. Exemplary antifungals are nystatin, lotrimin, ketoconazole, amphotericin B and analogs thereof. Antivirals include idoxuridine, amantadine, vidarabine, interferon, acyclovir, and analogues thereof. The polymeric coatings can also be used as a delivery system for iodine. . . . Other compounds that can be incorporated into the polymer include anticoagulants such as heparin, or anesthetics, preferably topical anesthetics such as lidocaine."); col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Col. 13:36-51; col. 14:47-53 ("In addition to antimicrobial agents and matrix forming materials, the coatings of the present invention may contain other compatible ingredients to advantage. For example, where anti-blood clotting activity is desired, heparin may be used, preferably at a level of 0.2%. Another useful ingredient is dextran sulfate, preferably also at a level of 0.2%."); col. 19:11-16; col. 36:32-46; col. 36:52-62; col. 37:8-28; col. 37:39-48; col. 37:58-60; col. 38:10-23; col. 38:31-38; col. 38:47-60; col. 40:37-38.

Hunter '981: Abstract ("The present invention provides compositions comprising an anti-angiogenic factor, and a polymeric carrier. Representative examples of anti-angiogenic factors include Anti-Invasive Factor, Retinoic acids and derivatives thereof, and paclitaxel."); col. 3:45-53 ("A wide variety of molecules may be utilized within the scope of the present invention as anti-angiogenic factors, including for example Anti-Invasive Factor, retinoic acids and their derivatives, paclitaxel including analogues and derivatives thereof, Suramin, Tissue Inhibitor of Metalloproteinase-1, Tissue Inhibitor-1 and Plasminogen Activator Inhibitor-2, and lighter "d group" transition metals."); col. 3:62-4:3 ("Within certain preferred embodiments, the compositions comprise a compound which disrupts microtubule function, such as, for example, paclitaxel, estramustine, colchicine, methotrexate, curacin-A, epothilone, vinblastine or tBCEV."); col. 4:253-55; col. 4:56-62; col. 5:33-36; col. 5:37-47; col. 11:56-59; col. 12:35-46; col. 12:55-59; col. 12:64-13:15; 13:16-27; col. 13:28-37; col. 13:40-52; col. 13:54-59; col. 13:60-14:22; col. 14:23-67 ("A wide variety of other anti-angiogenic factors may also be utilized

within the context of the present invention."); col. 15:3-11; col. 15:11-35 ("Anti-angiogenic compositions of the present invention may additionally comprise a wide variety of compounds in addition to the anti-angiogenic factor and polymeric carrier. For example, anti-angiogenic compositions of the present invention may also, within certain embodiments of the invention, also comprise one or more antibiotics, anti-inflammatories, anti-viral agents, anti-fungal agents and/or anti-protozoal agents."); col. 15:36-42 ("Anti-angiogenic compositions of the present invention may also contain one or more hormones such as thyroid hormone, estrogen, progesterone, cortisone and/or growth hormone, other biologically active molecules such as insulin, as well as Th1 (e.g. Interleukins-2, -12, and -15, gamma interferon) or Th2 (e.g., Interleukins-4 and -10) cytokines."); col. 15:43-16:30 ("Anti-angiogenic compositions of the present invention may also contain a wide variety of other compounds, including for example: . . . serotonin, endothelin . . . cytokine and/or growth factors . . . colchicine, anthracyclines and other antibiotics . . . DNA alkylating agents, topoisomerase inhibitors, purine antagonists and analogs, . . . immunosuppressive agents . . . sense or antisense oligonucleotides (e.g., DNA, RNA, nucleic acid analogues . . .), and inhibitors of transcription factor activity.").

Kinsella '608: Col. 5:43-57.

Lambert '922: Col. 3:15-32 ("Biologically active compounds suitable for use in the practice of the present invention include antithrombotic agents . . . anti-inflammatory drugs such as steroids, . . . colchicine . . . , retinoids . . . , probucol . . . , tyrophostins, antiproliferative compounds . . . , angiopeptin . . . , vasodilators . . . , and the like.").

Lambert '308: Page 5:15-28 ("Biologically active compounds suitable for use in the practice of the present invention include antithrombotic agents . . . anti-inflammatory drugs such as steroids, . . . colchicine . . . , retinoids . . . , probucol . . . , tyrophostins, antiproliferative compounds . . . , angiopeptin . . . , vasodilators . . . , and the like.").

WO 94/21309: Page 1:58-2:10 ("These medicines are used to further decrease the thrombogenicity of the stents (heparin, hirudin, streptokinase, urokinase, tpa and other anticoagulants) and to inhibit the inflammatory reaction caused by the stent (corticosteroids, antimitotics, angiopeptin and other anti-inflammatory drugs).").

Mitchell '711: Col. 2:44-3:6 ("It has been shown that heparin inhibits smooth muscle cell growth both in culture and in vivo."); col. 3:16-21 ("Rapamycin has also been shown to inhibit proliferation of vascular smooth muscle cells in vitro in response to mitogenic and heterotrophic factors, and in vivo following balloon catheterization of the carotid artery."); col. 3:24-31 ("This invention provides a method of preventing or treating hyperproliferative vascular disease in a mammal in need thereof by administering an antiproliferative effective amount of a combination of rapamycin and heparin to said mammal . . . via a vascular stent impregnated with a combination of rapamycin and heparin."); col. 5:3-10 ("Specifically, the combination of rapamycin and heparin is useful in preventing or treating intimal smooth muscle cell hyperplasia, restenosis, and vascular occlusion in a mammal, particularly following either biologically or mechanically mediated vascular injury . . ."); col. 5:11-17 ("While the results also show that rapamycin and heparin are each separately effective in preventing vascular smooth muscle proliferation . . .").

Morris '781: Col. 2:20-39 ("The following list identifies several of the agents for which favorable clinical results have been reported: lovastatin . . . thromboxane . . . eicosapentanoic acid . . . ciprostone . . . trapidil (a platelet derived growth factor) . . . angiotensin converting enzyme inhibitors . . . and low molecular weight heparin."); col. 3:45-50 ("This invention provides a method of preventing or treating hyperproliferative vascular disease in a mammal in need thereof by administering an antiproliferative effective amount of rapamycin to said mammal . . . via a vascular stent impregnated with rapamycin."); col. 3:50-56; col. 3:67-4:4 ("Rapamycin is also useful in preventing intimal smooth muscle cell hyperplasia, restenosis, and vascular occlusion resulting from mechanically mediated injury. In particular, for the prevention of restenosis following a percutaneous transluminal coronary angioplasty procedure."); col. 4:10-21 ("Other combinations containing rapamycin that are useful for preventing or treating hyperproliferative vascular disease will be apparent to one skilled in the art. These include, but are not limited to, using rapamycin in combination with other antiproliferative antimetabolites."); col. 9:66-10:33 ("The results in the tables above show that rapamycin, alone or in combination with mycophenoic acid, is useful in preventing restenosis following invasive procedures that disrupt vascular endothelial lining, such as percutaneous transluminal coronary angioplasty, vascular catheterization, vascular scraping, vascular surgery, or laser treatment procedures.").

Morris '182: Page 2:44-54 ("The following list identifies several of the agents for which favorable clinical results have been reported: lovastatin . . . thromboxane . . . eicosapentanoic acid . . . ciprostone . . . trapidil (a platelet derived growth factor) . . . angiotensin converting enzyme inhibitors . . . and low molecular weight heparin."); p. 3:24-27 ("This invention provides a method of preventing or treating hyperproliferative vascular disease in a mammal in need thereof by administering an antiproliferative effective amount of rapamycin to said mammal . . . via a vascular stent impregnated with rapamycin."); p.3:28-30; p. 3:45-52 ("Other combinations containing rapamycin that are useful for preventing or treating hyperproliferative vascular disease will be apparent to one skilled in the art. These include, but are not limited to, using rapamycin in combination with other antiproliferative antimetabolites."); p. 6:27-31 ("Specifically, rapamycin is useful in preventing or treating intimal smooth muscle cell hyperplasia, restenosis, and vascular occlusion in a mammal, particularly following either biologically or mechanically mediated vascular injury . . .").

Myler '563: Col. 4:56-57 ("Advantageously, the stent permits drug delivery directly to a preselected site in a body lumen."); col. 5:40-46; col. 13:15-17.

Palmaz '417: Col. 11:31-34 ("Such absorbable polymers could also contain various types of drugs, whereby as the coating is absorbed, or dissolves, the drug would be slowly released into the body passageway.").

Tice '330: Col. 4:65-6:27; col. 8:52-68 ("The method of claim 1, wherein said active agent is a biologically active agent selected from the group consisting of estrogens, progestins . . . , cardiovascular agents . . . , antibiotics . . . , prostaglandins . . . , cytotoxic drugs . . . , antigens and antibodies and enzymes.").

Tice '840: Col. 2:18-31 ("Suitable anti-inflammatory compounds include enzymes, hormones, phenylbutazones, salicylates, steroids, sulfonamides and the like."); col. 10:58-68 (" . .

. dissolving or dispersing an anti-inflammatory agent selected from the group consisting of a prednisolone, a triamcinolone, a dexamethasone and a β -methasone in a solvent . . .").

Tice '025: Col. 2:18-31 ("Suitable anti-inflammatory compounds include enzymes, hormones, phenylbutazones, salicylates, steroids, sulfonamides and the like."); col. 10:53-59 ("dissolving or dispersing an anti-inflammatory agent excluding corticosteroid anti-inflammatory agents and selected from the group consisting of enzymes, hormones, phenylbutazones, salicylates, steroids and sulfonamides in a solvent . . .").

Lapka '244: Col. 32:35-39 ("The process according to claim 8 wherein the core material is selected from the group consisting of cyclazocine, tetracycline, ehtisterone, digitoxin, antimony potassium tartrate, salmon calcitonin, ACTH, lypressin, sommatostatin, and insulin.").

Kent '189: Col. 1:18-26 ("More specifically it relates to microcapsules wherein the core contains water-soluble polypeptides which are lutenizing hormone-releasing hormones, or mammalian growth hormones or polypeptides having thymosin-like activity and optionally an organic acid or its salts, or an acidic, neutral or basic inorganic salt which is capable of modifying the hydrolysis rate of the polymer excipient, encapsulated by a biocompatible, biodegradable excipient."); col. 1:59-65; col. 2:19-32; col. 2:48-5:27 ("With regard to specific hormonally active polypeptides of interest herein, in a first instance there is the naturally occurring luteinizing hormone-releasing hormone (LH-RH) polypeptide and synthetic analogues thereof."); col. 5:28-7:59 ("A second group of hormonally active polypeptides of interest herein are mammalian growth hormones."); col. 7:60-10:12 ("A number of substances are known which, when administered to animals, enhance the ability of an organism's immune system to combat disease. Among these substances are crude extracts of mycobacteria, glycopeptides, and modification of glycopeptides which are derived therefrom, and "thymosins," a family of hormones secreted by a thymosin gland.").

Tice '268: Col. 11:47-59; col. 12:55-68.

Aebischer '486: Col. 3:7-18; col. 4:38-52 ("These include alpha 1-acid glycoprotein, various growth factors, second messenger substances, and second messenger inducers."); col. 4:53-65 ("Preferable nerve growth enhancers are growth factors, such as nerve growth factor (NGF) and fibroblast growth factor (FGF). Basic FGF (b-FGF) and acidic FGF (a-FGF) are particularly useful for this purpose."); col. 10:4-9.

Folkman '560: Col. 2:57-68; col. 4:27-68 ("The biologically active macromolecules that can be suitably employed . . . include proteins such as the peptide hormones that circulate in the blood of warm blooded animals such as insulin, glucagon, parathyroid and pituitary hormones, calcitonin, vasopressin, rennin, prolactin, growth hormone, thyroid stimulating hormone, corticotrophin, follicle stimulating hormone, luteinizing hormone and chorionic gonadotrophin . . .").

Cohen '496: Col. 4:40-65; col. 10:33-43.

Schiraldi '243: Col. 2:52-63 ("When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver

controlled/sustained dosages to the infected areas."); col. 3:3-10 ("A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 3:35-53; col. 4:7-12; col. 4:67-5:27.

Helwing '868: Col. 20:34-37 ("Along these lines, the inventive systems could be used to deliver not only general drugs, but cancer drugs, hormones, vitamins, fungicides and even used as a more durable sunscreen.").

Greco '135: Col. 1:29-2:59 ("The present Application is therefore an effort to further disclose and particularize this aspect of the invention, i.e., the development of the antibiotic bonded prosthesis utilizing an anionic surfactant and the oppositely charged drug, antibiotic or other agent or factor."); col. 3:8-19; col. 3:22-27; col. 4:43-5:26; col. 9:13-24.

Bawa '279: Col. 9:42-10:24; col. 11:55-12:9.

Aebischer '627: Col. 3:50-56; col. 6:60-7:2.

Wood '066: Col. 4:37-7:4 ("Of major importance to this PVA cryogel device invention are the specific components added to the PVA cryogel for controlled delivery. These components and their proposed function are listed in Table I."); col. 23:27- 26:7.

Strecker '746: Abstract; col. 1:63-2:2; col. 2:21-32; col. 7:1-10; col. 7:16-35; col. 8:16-18; col. 8:19-10:19.

Lambert '246: Abstract; col. 2:15-34; col. 2:53-65; col. 2:66-3:31 ("Biologically active compounds suitable for use in the practice of the present invention may fall anywhere on the spectrum from lipophilic to hydrophilic. . . . Biologically active compounds suitable for use in the practice of the present invention include . . ."); col. 3:32-48 ("Potential modifications which might aid in improving retention of the biologically active compound by the subject include: (1) adding lipid sidechains to the biologically active compound to enhance lipid solubility and retard diffusion from lipid membranes . . .").

Bellamkonda '029: Col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 4:18-20; col. 9:39-41; col. 11:41-50; col. 12:50-56.

Dayton '382: Abstract ("The bioactive substance may be selected from the group of . . . antithrombogenic agents . . ."); col. 4:34-41; col. 7:26-29; col. 7:34-43; col. 10:3-10.

Burt '036: p.4:9-28 ("A wide variety of molecules may be utilized within the scope of the present invention as anti-angiogenic factors . . ."); p.11:11-23.

Goldin '568: Col. 18:23-20:45; col. 21:22-31; col. 25:59-26:5 ("In general terms, the CND Controlled Release Device can be manufactured into therapeutic systems and shapes akin to those described above for delivering a physiologically and/or pharmacologically active macromolecule that produces one or more localized or systemic effects in animals . . .").

Zaffaroni '254: Col. 17:67 – 19:21 ("In the specification and the accompanying claims, the term, drug, broadly includes physiologically or pharmacologically active substances for producing a localized or systemic effect or effects in mammals including humans and primates; avians such as chicken and turkeys; valuable domestic household, sport or farm animals such as horses, dogs, cats, cattle, sheep and the like; or for administering to laboratory animals such as mice, monkeys, rats, guinea pigs; and the like. That is, the novel drug delivery device can be used for administering drugs that are physiologically or pharmacologically active at a point in near relation to the drug delivery device, or, for administering a systemically active drug which will produce a physiological or pharmacological response at a site remote from the point of application of the drug delivery device. The active drugs that can be administered by the drug delivery device of the invention include, without limitation: for example, drugs acting on the central nervous system such as, hypnotics and sedatives such as pentobarbital sodium, phenobarbital, enitabas, secobarbital, thiopental, etc.; heterocyclic hypnotics such as dioxopiperidines, and glutarimides; hypnotics and sedatives such as amides and ureas exemplified by diethylisovaleramide and .alpha.-bromoisovaleryl urea and the like; hypnotics and sedative alcohols such as carbomal, naphthoxyethanol, methylparaphenol and the like; and hypnotic and sedative urethans, disulfanes and the like; psychic energizers such as isocarboxazid, nialamide, phenelzine, imipramine, tranylcypromine, pargylene and the like; tranquilizers such as chloropromazine, promazine, fluphenazine reserpine, deserpidine, meprobamate, benzodiazepines such as chlordiazepoxide and the like; anticonvulsants such as primidone, diphenylhydantoin, ethotoin, pheneturide, ethosuximide and the like; muscle relaxants and anti-parkinson agents such as mephenesin, methocarbomal, trihexylphenidyl, biperiden, levo-dopa, also known as L-dopa and L-.beta.-3-4-dihydroxyphenylalanine, and the like; analgesics such as morphine, codeine, meperidine, nalorphine and the like; anti-pyretics and anti-inflammatory agents such as aspirin, salicylamide, sodium salicylamide and the like; local anesthetics such as procaine, lidocaine, naepaine, piperocaine, tetracaine, dibucaine and the like; antispasmodics and antiulcer agents such as atropine, scopolamine, methscopolamine oxyphenonium, papaverine, prostaglandins such as PGE.sub.1, PGE.sub.2, PGF.sub.1.sub..alpha., PGF.sub.2.sub..alpha., PGA and the like; anti-microbials such as penicillin, tetracycline, oxytetracycline, chlorotetracycline, chloramphenicol, sulfonamides and the like; anti-malarials, such as 4-aminoquinolines, 8-aminoquinolines and pyrimethamine; hormonal agents such as prednisolone, cortisone, cortisol and triamcinolone; androgenic steroids, for example, methyltestosterone, fluoximesterone and the like; estrogenic steroids, for example, 17.beta.-estradiol and ethinyl estradiol; progestational steroids, for example 17.alpha.-hydroxyprogesterone acetate, 19-nor-progesterone norethindrone and the like; sympathomimetic drugs such as epinephrine, amphetamine, ephedrine, norepinephrine and the like; cardiovascular drugs, for example, procainamide, amyl nitrate, nitroglycerin, dipyrindamole, sodium nitrate, mannitol nitrate and the like; diuretics, for example, chlorothiazide, flumethiazide and the like; antiparasitic agents such as bephenium hydroxynaphthoate and dichlorophen, dapsone and the like; neoplastic agents such as mechlorethamine, uracil mustard, 5-fluorouracil, 6-thioguanine, procarbazine and the like; hypoglycemic drugs such as insulins, protamine zinc insulin suspension, globin zinc insulin,

isophane insulin suspension, and other art known extended insulin suspensions, sulfonylureas such as tolbutamide, acetohexamide, tolazamide, and chlorpropamide, the biguanides and the like; nutritional agents such as vitamins, essential amino acids, essential fats and the like; and other physiologically or pharmacologically active agents. Also, the drugs can be present as the pharmacologically acceptable derivatives, such as ethers, esters, amides, acetals, etc. that lend themselves to passage into the circulatory system. For highly water soluble drugs, it is preferable that the wall or the reservoir, or both be formed from a material that is substantially impermeable to water to essentially prevent dilution of the drug by absorption of body fluids into the device with an accompanying decrease in drug release rate."); col. 19: 22-49.

Aebischer: p. 283 (disclosing treating factors such as FGF).

Dev: p. 273 ("To study the kinetics of drug delivery, we used two lipid soluble compounds: forskolin and etretinate.").

Claim 3 [3A]: The device of claim 1 whereby said layer is capable of release of the at least one treating material by lysis of a chemical bond.

Where Found in the Prior References:

Peterson '166: Abstract ("A time-release chemical delivery system in which a bioactive compound is attached to a polymeric biodegradable carrier by a hydrolysable bond is disclosed. The bioactive compound can either be bound directly to the polymer or be attached to the polymer via a spacer group."); col. 1:28-38; col. 1:51-55 ("Another object of the instant invention is to provide a bioactive compound via covalent bonding to a polymeric backbone so that upon hydrolysis of said covalent bond said bioactive compound is released in active, unmodified form."); col. 1:60-62; col. 1:67-col. 2:2; col. 2:40-50 ("A further requirement of the polymeric carriers are that they contain a pendant group to which a reactive compound may be directly attached by a hydrolyzable bond or to which a spacer unit may be attached with the reactive compound attached to the spacer unit by a hydrolysable bond. Typically, the space [sic] unit will also be attached to the polymeric carrier by a hydrolyzable bond."); col. 2:51-60; col. 3:67-4:2; col. 4:3-7 ("The use of a spacer group may also provide desirable changes in drug release rate by allowing ease of hydrolysis of the drug."); col. 4:8-19; col. 4:56-5:2; col. 6:28-55; col. 6:55-62 ("Since the proximity of the reactive carboxyl group to the polymer backbone may interfere with the addition of a bioactive compound, especially a large molecule, and with the subsequent hydrolysis of a covalent bond formed by such condensation reaction, the use of a spacer group, preferably linear in nature, may be preferred in this invention."); col. 6:65-col.7:28 ("To be effective as hydrolysable carriers the polymers of this invention must have pendant reactive sites to which a bioactive compound may be attached. . . . These functional groups may react with functional groups of the bioactive compound to form a hydrolysable bond. The hydrolysable bond may be direct between the pendant group of the polymer and the reactive

compound or it may be first reacted with a spacer unit which contains a similar reactive functional group. . . . The reactivity of the reactive sites is also affected by the distance of the reactive site from the backbone of the polymer."); col. 7:32-53 ("Spacer groups may be utilized in the practice of the instant invention to provide a hydrolysable unit which spaces the reactive compound further from the carrier backbone. As indicated hereinabove, the polymeric units may contain long pendant chains which place the reactive site on the pendant group further away from the carrier backbone. . . ."); col. 7:57-62 ("Bioactive compounds useful in this invention are those which contain a group which may react to form a bond with a pendant group or a spacer group. The bond is preferably hydrolysable and in particular are esters, including sulfates or phosphate esters, amides, carbonates and urethane bonds."); col.8:25-28 ("The reactive compound which is released over a period of time in the instant invention may be one which has a pharmacological affect upon the host, for example, a contraceptive drug in an animal."); col. 8:34-49 ("Factors which affect the release rate and the rate of absorption into the body of the host include . . . the composition of the polymer backbone, the length and character of the spacer groups and the character of the pendant groups The spacing of the bulky drug or chemically reacted compound from the polymer also affects the rate of release."); col. 11:25-12:4 (" . . . a bioactive compound chemically attached to said carrier by a hydrolysable bond, said bioactive compound containing a group which reacts with a group on the biodegradable polymer to form a hydrolysable bond and being effective in small dosages to produce a biological effect within said host upon release into the host by hydrolysis of the hydrolyzable bond."); col. 12:14-24 ("The chemical delivery system of claim 1 wherein said bioactive compound is indirectly coupled to said carrier by a hydrolyzable bond to a spacer compound. . . . The chemical delivery system of claim 7 wherein said spacer compound is coupled to said bioactive compound by a hydrolyzable bond."); col. 12:28-30.

Schwartz '823: Col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:64-4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof."); col. 7:1-4 ("In yet another aspect of the present invention, various therapeutic substances can be incorporated in or applied to the polymeric film to provide such substances to the blood or to the lumen wall."); col. 7:14-25 ("Application of the therapeutic substance to the film can include applying it on the surface of the film or incorporating it into the film as it is made. For example, microcapsules can be used to carry the therapeutic substance either in or on the film and to provide timed-release of the substance to the blood, or to the blood vessel or both."); col. 7:25-34 ("Microcapsules containing one type of therapeutic substance could be provided on one side of the film and microcapsules containing another therapeutic substance could be incorporated on the other side of the film, thus providing a stent according to the present invention which provides one type of therapeutic substance (e.g. an anti-thrombotic drug) to the blood and another type of therapeutic substance (e.g. an antiproliferative drug) to the

vessel wall."); col.8:5-11 ("The resulting stent has microcapsules containing one therapeutic substance on the inside (and able to contact blood once implanted in a blood vessel) and microcapsules containing a second therapeutic substance on the outside (and able to contact the vessel wall when implanted in contact with the vessel wall)."); col. 8:46-47.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14; col. 4:53-55; col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-33; col. 5:34-6:23 ("Many polymers can also be used to make the sheath, including biodegradable and non-degradable polymers. The polymer is selected depending on the drug selected, the polymer's compatibility with a subject and the ultimate pharmacologic effect desired. . . . Another alternative would be to use a polymer which is biodegradable over a short period of time. Naturally, the opposite characteristics would be selected for a desired prolonged release. The characteristics of the particular polymer for these purposes is well known to the skilled artisans or can be determined by reference to standard references . . ."); col. 6:39-41 ("The initial prototype is a sleeve of polymer, either degradable or non-degradable, that covers the entire stent (Fig. 3)"); col. 6:64-68 ("The duration of drug delivery is accurately predicted by the characteristics of the polymer. For example, if the polymer is biodegradable, then the rate and duration of drug delivery is related to the thickness of the polymer."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface."); col. 8:23-54; col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33 ("In combination, a hollow tubular stent having a predetermined length and a separate sheath removably encompassing at least a portion of said hollow tubular stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug."); col. 11:11-12 ("14. The sheath of claim 1, wherein the polymer is biodegradable."); col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 5:4-9 ("The primary function of the sheet of polymeric material is to deliver therapeutic agents or drugs to help prevent thrombosis and/or restenosis."); col. 5:49-6:25 ("The polymeric material is preferably bioabsorbable, and is preferably loaded or coated with a therapeutic agent or drug . . ."); col. 7:23-25; col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:63-2:6 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery. The prostheses may be completely biodegradable or may be bioabsorbable in whole or incorporated into the lumen wall as a result of tissue overgrowth, i.e. endothelialization. Alternatively, the prostheses may be biostable in which case the drug is diffused out from the biostable materials in which it is incorporated."); col. 2:28-30 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 2:55-58; Fig. 5; col. 6:5-10 ("When drugs are delivered locally via the prosthesis of the invention, they may be at therapeutic levels at the diseased site while at the lower limits of detectability in the bloodstream. So little drug is required for effective local treatment of a lumen that the drug may not be detectable in blood samples."); col. 6:36-38; col. 6:59-63 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously. the polymer may be biostable or bioabsorbable. If biostable, the drug would diffuse out of the polymer."); col. 6:64-67; col. 7:19-23; col. 7:53-55 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 7:59-8:25; col. 8:26-31 ("The

compound which is preferred is a polyphosphate ester. Polyphosphate ester is a compound such as that disclosed in U.S. Pat. Nos. 5,176,907; 5,194,581; and 5,656,765 issued to Leong which are incorporated herein by reference. Similar to polyanhydrides, polyphosphate ester is being researched for the sole purpose of drug delivery."); col. 8:40-9:22 ("It is the hydrolytic instability of the phosphorous ester bond which makes this polymer attractive for controlled drug release applications. A wide range of controllable degradation rates can be obtained by adjusting the hydrophobicities of the backbones of the backbones of the polymers and yet assure biodegradability. The functional side groups allow for the chemical linkage of drug molecules to the polymer."); col. 12:12-15.

Berg '354: Page 2:27-31 ("Other methods of providing therapeutic substances to the vascular wall include simple heparin-coated metallic stents, whereby a heparin coating is ionically or covalently bonded to the stent. Still other methods of providing therapeutic substances to the vascular wall by means of stents have also been proposed such as in US-A-5102417 (Palmaz), WO-91/12779 "Intraluminal Drug Eluting Prosthesis" and WO-90/133332 "Stent With Sustained Drug Delivery".); p. 3:7-9; p. 3:22-23 ("It also provides a drug-containing stent which allows for a sustained release of the drug to vascular tissue."); p. 4:25-27 ("The ratio of therapeutic substance to polymer in the solution will depend on the efficacy of the polymer in securing the therapeutic substance onto the stent and the rate at which the coating is to release the therapeutic substance to the tissue of the blood vessel."); p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Abstract ("A stent made of biodegradable material includes a drug that is released at a rate controlled by the rate of degradation of the biodegradable material."); col. 1:61-63; col. 2:6-8 ("The mechanism of biodegradation is described as hydrolysis resulting in degradable products excreted in urine or reabsorbed into tissues."); col. 2:49-52 ("Also desired are stents which can deliver drugs or biologically active agents at a controlled rate to blood passing through the vessel lumen as well as to the vessel wall."); col. 2:56-61 ("The biodegradable stent is made from at least one biodegradable material that is also biocompatible and includes a drug which is released into the lumen of the vessel at a rate controlled by the rate of degradation of the biodegradable material."); col. 3:11-12 ("The rate of drug release is controlled by the rate of degradation of the biodegradable materials."); col. 3:53-55; col. 4:12-14; col. 4:23-25 ("The present invention further includes a main body having more than one biodegradable interior film layer."); col. 4:65-5:5 "In the most preferred embodiment, the biodegradable stent of the present invention is made of biodegradable materials that are also biocompatible. By biodegradable is meant that a material will undergo breakdown or decomposition into harmless compounds as part of a normal biological process"); col. 5:11-19 ("Suitable biodegradable materials for the main body of the stent of the present invention include polylactic acid, polyglycolic acid (PGA), collagen or other connective proteins or natural materials, polycaprolactone, hylauric acid, adhesive proteins, co-polymers of these materials as well as composites and combinations thereof and combinations of other biodegradable polymers."); col. 5:21-37; col. 5:38-45 ("Consequently, the presence of different biodegradable materials in the stent permits the stent to degrade in a predictable, orchestrated fashion."); col. 5:46-54 ("As the stent biodegrades, drugs are administered to the surrounding tissue or to the

blood stream. Thus, the rate of drug release is controlled by the rate of degradation of the biodegradable materials."); col. 6:3-8; col. 6:45-59; col. 7:2-9; col. 7:32-8:9; col. 8:27-30.

Ding '536: Abstract ("In one embodiment, the surface is provided with sites of high electronegativity species by coating with fluorosilicone which aid in controlled elution, particularly the initial release rate, and reduce thrombogenic activity."); col. 2:38-42 ("Such an approach is described by Winters, et al., in U.S. Pat. Nos. 5,182,317; 5,262,451 and 5,338,770 in which the amine functional groups of the active material are covalently bonded using a polyethylene oxide (PEO) on a siloxane surface."); col. 2:43-46 ("Another approach is described in U.S. Pat. No. 4,613,665 to Larm in which heparin is chemically covalently bound to impart a non-thrombogenic surface to the material."); col. 3:19-27 ("Accordingly, it is a primary object of the present invention to provide a coating and process for coating a stent to be used as a deployed stent prosthesis, the coating being capable of effective controlled long-term delivery of biologically active materials. Another object of the invention is to provide a coating and process for coating a stent prostheses using a biostable hydrophobic elastomer in which biologically active species are incorporated within a coating."); col. 6:16-27 ("The mechanism of incorporation of the biologically active species into the surface coating and egress mechanism depend both on the nature of the surface coating polymer and the material to be incorporated. The mechanism of release also depends on the mode of incorporation. The material may elute via interparticle paths or be administered via transport or diffusion through the encapsulating material itself."); col. 6:28-34; col. 6:35-48; col. 10:35-40 ("In addition, because of the negative charges on the heparin itself, the electro-negativity of the fluorosilicone topcoat may be, at least in part, responsible for the modified heparin release kinetic profile."); col. 12:62-67 ("Whereas the polymer of the coating may be any biostable elastomeric material capable of being adhered to the stent material as a thin layer, hydrophobic materials are preferred because it has been found that the release of the biologically active species can generally be more predictably controlled with such materials. Preferred materials include silicone rubber elastomers and biostable polyurethanes specifically.").

Dinh '227: Col. 2:26-32; col. 3:10-14; col. 5:53-55 ("Suitable polymers could also be biodegradable polymers such as polyphosphate ester, polyhydroxybutyrate valerate, polyhydroxybutyrate-co-hydroxyvalerate and the like."); col. 6:13-22; col. 6:32-50; col. 6:50-56; col. 7:10-13 ("The adhesion of the coating and the rate at which the drug is delivered can be controlled by the selection of an appropriate bioabsorbable or biostable polymer and by the ratio of drug to polymer in the solution."); col. 7:13-23; col. 7:30-44; col. 7:45-51 ("The polymer used can be bioabsorbable or biostable polymer. Suitable bioabsorbable polymers include poly(L-lactic acid), poly(lactide-co-glycolide) and poly(hydroxybutyrate-co-valerate). Suitable biostable polymers include silicones, polyurethanes, polyesters, vinyl homopolymers and copolymers, acrylate homopolymers and copolymers, polyethers and cellulotics."); col. 9:17-18; col. 12:38-50.

[Domb '055: Abstract ("Preferred polymeric coatings are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); col. 3:54-62 ("In the preferred embodiments, these have utilized bioerodible polymers as the matrix for the drug to be released, usually as a function of diffusion and erosion of the polymer. The advantage of these drug delivery systems is that

they provide a sustained/continuous release of drugs locally and at a relatively high concentration in areas of the body, without systemic side-effects, throughout the duration of their release."); col. 4:11-13 ("It is a further object of the present invention to provide medical devices having prolonged low-dose, localized release of anti-microbial and anti-inflammatory agents."); col. 4:33-36; col. 5:27-33; col. 5:41-45 ("The drug-loaded polymer provides a sustained release of steroids and antibiotics locally and at a relatively high concentration in that area which is critically affected, without the side-effects of the systemic administration of the same drugs, throughout the duration of intubation."); col. 5:49-54; col. 5:60-6:1 ("An esophageal silicone stent coated with a film of polymer can be used to provide a site-specific controlled release of corticosteroids and antibiotics."); col. 6:3-7; col. 6:24-26 ("Examples of suitable polymers include ethylene vinyl acetate, polyurethane, silicones, hydrogels, polyurethane, and polyvinyl chloride."); col. 6:42-45 ("Release is a function of diffusion of the agent from the polymeric matrix, and varies by size, concentration and solubility of the agent, as well as by thickness and chemical composition of the polymeric matrix."); col. 7:10-20; col. 7:25-29; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 11:36-38 ("The medical device of claim 1, wherein the polymer is selected from the group consisting of polyurethane, ethylene vinyl acetate, silicones, hydrogels, and polyvinyl chloride."); col. 11:39-44; col. 12:1-7; col. 12:11-22; col. 12:23-25; col. 12:26-31; col. 12:32-42.

Fox '096: Abstract ("A method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers, and antimicrobial agents . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 3:55-67 ("The polymeric coating agent component of the coating vehicle of the present invention is selected from the group consisting of biomedical polyurethanes, biomedical silicones, biodegradable polymers and combinations thereof."); col. 4:30-5:35; col. 7:22-25; col. 7:28-32; col. 11:34-48 ("Suitable biodegradable polymers include the homopolymers poly(glycolic acid), poly(D-lactic acid), poly(D,L-lactic acid), poly(D,L-ethyl-glycolic acid), poly(dimethylglycolic acid), poly(D,L-methylethylglycolic acid), and poly(E-caprolactone), as well as biodegradable polyhydroxy butyric acid and mixtures thereof. A preferred biodegradable polymer is polylactic acid (PLA)."); col. 11:51-56 ("The biodegradable polymer modulates the rate of release of antimicrobial drugs."); Table IV; col. 12:24-41 ("Suitable biomedical poly(lactic) polymers include the poly(L-lactide), poly(D-lactide) and the poly (D-L-lactic acid). . . . The poly(lactic acid) polymers are bioerodible, and while they can be used alone, it is preferred that they be combined with either a biomedical polyurethane or a biomedical silicone."); col. 15:20-33 ("It

will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages."); col. 18:19-25; col. 20:54-58; col. 28:13-18; col. 29:38-40 (Adding a biodegradable material containing anti-microbial agents to the adhesive to provide controlled-release through degradation."); col. 36:21-31; col. 36:47-51; col. 36:65-37:7; col. 37:29-31; col. 37:56-57; col. 37:63-65; col. 37:66-38:9; col. 38:24-30; col. 39:39-41; col. 40:33-34; col. 40:39-42.

Hunter '981: Abstract; col. 3:42-61 ("A wide variety of molecules may be utilized within the scope of the present invention as anti-angiogenic factors, including for example Anti-Invasive Factor, retinoic acids and their derivatives, paclitaxel including analogues and derivatives thereof, Suramin, Tissue Inhibitor of Metalloproteinase-1, Tissue Inhibitor-1 and Plasminogen Activator Inhibitor-2, and lighter "d group" transition metals. Similarly, a wide variety of polymeric carriers may be utilized, representative examples of which include poly (ethylene-vinyl acetate) (40% cross-linked), poly (D,L-lactic acid) oligomers and polymers, poly (L-lactic acid) oligomers and polymers, poly(glycolic acid), copolymers of lactic acid and glycolic acid, poly(caprolactone), poly(valerolactone), poly(anhydrides), copolymers of poly(caprolactone) or poly(lactic acid) with polyethylene glycol, and blends thereof."); col. 5:27-32; col. 12:23-35 ("As noted above, the present invention provides compositions comprising an anti-angiogenic factor, and a polymeric carrier."); col. 16:31-56 ("[A]nti-angiogenic compositions of the present invention are provided in a wide variety of polymeric carriers, including for example both biodegradable and non-biodegradable compositions. Representative examples of biodegradable compositions include albumin, gelatin, starch, cellulose, dextrans, polysaccharides, fibrinogen, poly (D,L lactide), poly (D,L-lactide-co-glycolide), poly (glycolide), poly (hydroxybutyrate), poly (alkylcarbonate) and poly (orthoesters) Representative examples of nondegradable polymers include EVA copolymers, siliconerubber and poly (methylmethacrylate). Particularly preferred polymeric carriers include poly (ethylene-vinyl acetate)(40% cross-linked), poly(D,L-lactic acid) oligomers and polymers, poly (L-lactic acid) oligomers and polymers, poly (glycolic acid), copolymers of lactic acid and glycolic acid, poly (caprolactone), poly (valerolactone), polyanhydrides, copolymers of poly (caprolactone) or poly (lactic acid) with polyethylene glycol and blends thereof."); col. 16:31-56; col. 16:66-17:6 ("Anti-angiogenic factors may be linked by occlusion in the matrices of the polymer, bound by covalent linkages, or encapsulated in microcapsules. Within certain preferred embodiments of the invention, anti-angiogenic compositions are provided in non-capsular formulations such as microspheres . . . pastes, threads of various size, films and sprays."); col. 17:7-26; col. 17:41-43 ("Anti-angiogenic compositions may also be prepared, given the disclosure provided herein, for a variety of other applications."); col. 18:15-49 ("Within further aspects of the present invention, polymeric carriers are provided which are adapted to contain and release a hydrophobic compound, the carrier containing the hydrophobic compound in combination with a carbohydrate, protein or polypeptide. Within certain embodiments, the polymeric carrier contains or comprises regions, pockets, or granules of one or more hydrophobic compounds."); col. 47:58-49:7; col. 56:45-57; col. 57:17-31; col. 59:65-60:48; col. 59: 32-59 ("Poly(e-caprolactone) is an aliphatic polyester which can be degraded by hydrolysis under physiological conditions and it is non-toxic and tissue compatible."); col. 69:19-62; col. 77:43-55 ("The release

of paclitaxel, in this case, is dominated by polymer degradation."); col. 78:58-79:5 ("Although not specifically set forth above, a wide variety of other polymeric carriers may be manufactured, including for example . . ."); col. 84:62-86:24; col. 86:60-67.

Kinsella '608: Col. 11:18-24 ("Drug delivery systems that can be valuable include drug-impregnated polymer-coated metallic stents [and] biodegradable drug-eluting polymer stents . . .").

Kowligi '782: Col. 4:16-27 ("In regard to elastomeric coating 38 shown in Fig. 2, such elastomeric coating is selected to be a biocompatible elastomers and may be selected from the group consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 10:18-27; col. 10:28-32 ("The implantable vascular graft recited by claim 1 wherein said elastomers is selected from the group of elastomers consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 10:43-50; col. 10:60-67.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 1:46-55 ("Release of heparin from intravascular catheters in quantities sufficient to decrease thrombosis on the catheter has been achieved by either covalently bonding a charged molecule to a polymer or incorporating a large nonmobile charged molecule on the surface of the polymer . . ."); col. 1:62-65; col. 2:16-35; col. 2:40-50 ("In accordance with the present invention, there is provided a method for preparing a system suitable for localized delivery of biologically active compounds to a subject."); col. 2:55-67; col. 3:8-12; col. 3:29-49; col. 4:10-17; col. 7:29-32; col. 7:38-41; col. 8:62-9:19 ("Adventitia overlying the stent contained 360 times the concentration of forskolin in the blood and 305 times the concentration of forskolin in the contralateral artery. . . . In a similar model, etretinate, a retinoic acid analog, develops concentrations in the media of 250 ng/mg tissue at 24 hours. At 24 hours, this concentration was over 2000 times the concentration in the blood."); col. 9:31-37 ("These data demonstrate that a polyurethane coated nitinol stent is capable of delivering a lipophilic drug in high local concentration in the vessel wall. The large 450 fold differential of local tissue levels of forskolin over blood levels reflects the capability of this delivery system to provide high local concentration and potentially higher efficacy, with lower risk of systemic side effects."); col. 12:21-22 ("The method in accordance with claim 1, wherein the biologically active compound is a lipophilic compound."); col. 12:27-30 ("The method in accordance with claim 1, wherein the biologically active compound is a hydrophilic compound, said method further comprising linking the hydrophilic compound to a lipophilic carrier.").

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p.

2:10-19 ("Release of heparin from intravascular catheters in quantities sufficient to decrease thrombosis on the catheter has been achieved by either covalently bonding a charged molecule to a polymer or incorporating a large nonmobile charged molecule on the surface of the polymer . . ."); p. 2:25-30; p. 3:10-31 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); p. 4:2-12; p. 4:17-31; p. 15:25-16:14 ("Adventitia overlying the stent contained 360 times the concentration of forskolin in the blood and 305 times the concentration of forskolin in the contralateral artery. . . . In a similar model, etretinate, a retinoic acid analog, develops concentrations in the media of 250 ng/mg tissue at 24 hours. At 24 hours, this concentration was over 2000 times the concentration in the blood."); p.16:27-34 ("These data demonstrate that a polyurethane coated nitinol stent is capable of delivering a lipophilic drug in high local concentration in the vessel wall. The large 450 fold differential of local tissue levels of forskolin over blood levels reflects the capability of this delivery system to provide high local concentration and potentially higher efficacy, with lower risk of systemic side effects."); claim 14 ("The method in accordance with claim 1, wherein the biologically active compound is a lipophilic compound."); claim 16 ("The method in accordance with claim 1, wherein the biologically active compound is a hydrophilic compound, said method further comprising linking the hydrophilic compound to a lipophilic carrier."); claim 26.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8; p. 1:56-58.

Mitchell '711: Col. 6:24-28 ("Suitable solid carrier include, for example, calcium phosphate, magnesium stearate, talc, sugars, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, sodium carboxymethyl cellulose, polyvinylpyrrolidone, low melting waxes and ion exchange resins.").

Morris '781: Col. 10:50-54 ("Suitable solid carriers include, for example, calcium phosphate, magnesium stearate, talc, sugars, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, sodium carboxymethyl cellulose, polyvinylpyrrolidone, low melting waxes and ion exchange resins.").

Morris '182: Page 6:54-56 ("Suitable solid carriers include, for example, calcium phosphate, magnesium stearate, talc, sugars, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, sodium carboxymethyl cellulose, polyvinylpyrrolidone, low melting waxes and ion exchange resins.").

Myler '563: Col. 4:57-59; col. 4:60-67 ("[T]he stent can be provided with a solid drug carrier such as an impregnated porous solid wall or sponge for timed drug delivery."); col. 5:39-41 ("For the above reasons, even the expanded pores for drug delivery should be small enough to maximize or prevent cell penetration, but large enough for drug delivery."); col. 13:15-18 ("The exterior coating which will contact the arterial wall is optionally made porous to enable the release of drugs to the treatment site.").

Palmaz '417: Col. 11:8-11; col. 11:26-34 ("Examples of biologically compatible coatings would include coatings made of absorbable polymers such as those used to manufacture

absorbable sutures. Such absorbable polymers include polyglycoides, polyacoides, and copolymers thereof. Such absorbable polymers could also contain various types of drugs, whereby as the coating is absorbed, or dissolves, the drug would be slowly released into the body passageway.").

Tice '330: Col. 3:20-33 ("A preferred group of polymeric wall forming materials includes those which are biodegradable such as aliphatic polyesters including polylactide, polyglycolide, polycaprolactone and copolymers thereof."); col. 8:38-51.

Thies '317: Abstract ("The capsules provide controlled release of the active agent over a prolonged period of time."); col.1:15-19 ("The art of encapsulation has developed various processes and methods for individually coating particular matter for purposes of controlled release or metering out of an active agent over a prolonged period."); col. 2:26-38; col. 2:43-47; col. 2: 48-51; col. 3:41-4:2; col. 6:35-39 ("Therefore, the presence of a soluble alkali metal silicate in the interior of the capsule causes much of the capsule coating material to simply disappear upon immersion in water thereby causing accelerated release of the active agent."); col. 7:36-11:68; col. 12:10-40; col. 13:4-14:3.

Tice '840: Col. 2:32-34; col. 2:38-55 ("The polymeric matrix material of the microparticles of the present invention must be a biocompatible and biodegradable polymeric material. . . . Suitable examples of polymeric matrix materials include poly (glycolic acid), poly-d,l-lactic acid, copolymers thereof, copolyoxalates, polycaprolactone, poly (lactic acid-caprolactone), and the like."); col. 2:56-3:8 ("The molecular weight of a polymer is also important from the point of view that molecular weight influences the biodegradation rate of the polymer. The drug can also be released from the microparticles as the polymeric excipient bioerodes. By an appropriate selection of polymeric materials a microparticle formulation can be made such that the resulting microparticles exhibit both diffusional release and biodegradation release properties."); col. 10:56-11:15; col. 12:6-9.

Tice '025: Col. 2:32-34; col. 2:38-55 ("The polymeric matrix material of the microparticles of the present invention must be a biocompatible and biodegradable polymeric material. . . . Suitable examples of polymeric matrix materials include poly (glycolic acid), poly-d,l-lactic acid, copolymers thereof, copolyoxalates, polycaprolactone, poly (lactic acid-caprolactone), and the like."); col. 2:56-3:8 ("The molecular weight of a polymer is also important from the point of view that molecular weight influences the biodegradation rate of the polymer. The drug can also be released from the microparticles as the polymeric excipient bioerodes. By an appropriate selection of polymeric materials a microparticle formulation can be made such that the resulting microparticles exhibit both diffusional release and biodegradation release properties."); col. 10:51-11:5; col. 12:1-4.

Lapka '244: Abstract; col. 2:35-63; col. 4:35-57 ("Among the bioabsorbable polymer materials suitable for use in the invention may be mentioned poly(lactic acid) or polylactic acid polymers, such as dl-poly(lactic acid) (or poly(dl-lactic acid)) polymers, poly-(glycolic acid) polymers, poly(hydroxybutyric acid) polymers and lactide/glycolid copolymers."); col. 4:58-5:5 ("The solid injectable drug material which constitutes the core material of the microcapsules may be any such injectable drug material for which it is desired to establish a long-acting, sustained

release delivery system."); col. 32:5-16; col. 32:20-21; col. 32:28-34; col. 32:35-39 ("The process according to claim 8 wherein the core material is selected from the group consisting of cyclazocine, tetracycline, ehtisterone, digitoxin, antimony potassium tartrate, salmon calcitonin, ACTH, lypressin, sommatostatin, and insulin.").

Kent '189: Abstract; col. 1:12-28 ("The invention relates to a microcapsule composition comprising a core containing at least one water-soluble, hormonally active polypeptide and optionally a polymer hydrolysis modifying agent encapsulated in a biodegradable, biocompatible copolymer excipient. These compositions have sustained release characteristics. More specifically it relates to microcapsules wherein the core contains water-soluble polypeptides which are lutenizing hormone-releasing hormones, or mammalian growth hormones or polypeptides having thymosin-like activity and optionally an organic acid or its salts, or an acidic, neutral or basic inorganic salt which is capable of modifying the hydrolysis rate of the polymer excipient, encapsulated by a biocompatible, biodegradable excipient."); col. 1:50-58; col. 2:4-7 ("The encapsulating material may be a synthetic polymer comprising either poly(o-hydroxycarboxylic acids), poly(lactones), poly(acetals), poly(orthoesters) or poly(orthocarbonates)."); col. 11:5-38; col. 11:39-13:35 ("The number and type of encapsulating excipients which may be effectively used to practice this invention is limited only by the requirements that the material be biocompatible and biodegradable. . . . Various combinations of alpha hydroxycarboxylic acids and certain lactones can be condensed to form such polymers, particularly lactic acid and glycolic acid or combinations thereof. . . . Similar biocompatible polymers based on glycolic acid and glycerol and the like are also known. . . . Several new biocompatible, biodegradable polymers derived from polyorthoesters and polyorthocarbonates also may be effectively used as encapsulating excipients in the practice of this invention. . . . There are also known polyacetals and polyorthoesters useful for this purpose . . ."); col. 17:42-18:67.

Tice '268: Abstract ("A compatible, biodegradable microcapsule delivery system for active ingredients, including hormonally active peptides, proteins, or other bioactive molecules . . ."); col. 1:32-46 ("More recently a polymer of poly(D,L-lactide-coglycolide) (DL-PLG), which is biodegradable and biocompatible with living tissue, has been used in microcapsules for longer acting delivery systems. Systems of microencapsulated active ingredients in polymers and copolymers have been used to achieve controlled release of chemical and biological pharmaceuticals."); col. 1:47-2:14 ("The microcapsule systems described in the above-publications all share a common feature in that the release of the compound is controlled by the porosity and/or erosion of a polymer continuum."); col. 2:45-53; col. 3:40-47 ("It should be noted, however, that other polymers besides poly(D,L-lactide-co-glycolide) may be used. Examples of such polymers include, but are not limited to: polyacetal polymers, polyorthoesters, polyesteramides, polycaprolactone and copolymers thereof, polycarbonates, polyhydroxybuterate and copolymers thereof, polymaleamides, copolyaxalates and polysaccharides."); col. 11:15-41.

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); col. 3:13-18; col. 3:34-38 ("In a preferred technique, one or more finishing coats of a second solution containing the same or another biocompatible polymer without the

carrier is applied to provide an impermeable or substantially less permeable outer surface."); col. 4:29-34 ("In this embodiment, active factor 26 is incorporated within the membrane wall 12. The outer membrane surface 28 is nonporous, while porous inner membrane surface 22 allows for the diffusion therethrough of active factor 26."); col. 4:66-5:11 ("The membrane of the channel may be fabricated from any biocompatible polymers, such as, for example, polyethylene vinyl-acetate (EVA). . . . Preferable acrylates include methacrylates or hydroethylmethacrylates. The membrane instead may be composed of a bioresorbable biocompatible polymer, such as a polyanhydride, polyester, or mixtures thereof."); col. 5:18-28 ("In a preferred embodiment of the invention, the outer surface of the membrane is impermeable to solutes of any size, while the inner membrane surface contains pores [that] enable the active factors to diffuse out of the membrane and into the lumen of the channel."); col. 5:44-6:10; col. 6:17-22 ("The layering procedure allows deposition of an impermeable coat on the outer surface of the device, insuring that the active factors incorporated into the membrane walls will be inhibited from diffusing through the external surface, and will diffuse only through the inner membrane surface into the lumen of the channel."); col. 9:18-10:3; col. 10:10-12.

Folkman '560: Col. 1:56-2:23; col. 2:43-68; col. 3:18-23 ("The polymer matrixes, which are suitably used in the present invention, are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:36-51 ("Typical polymeric material suitable for forming the matrix . . . include . . . alkylene-vinyl acetate copolymers . . . crosslinked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:52-4:26 ("In the presently preferred embodiment the polymeric materials useful for forming the matrix are the ethylene vinyl ester copolymers of the general formula . . ."); col. 8:17-18; col. 11:56-12:20; col. 12:28-31; col. 12:36-43; col. 12:52-54 ("The therapeutic system for the administration of insulin according to claim 1, wherein the polymeric matrix is ethylene-vinyl acetate copolymer."); col. 12:59-61.

Cohen '496: Abstract; col. 2:46-66 ("In general, the invention features an improved method of making such a body, in which a biologically active material and the polymer below the glass transition temperature of the polymer and compressing the mixture above the glass transition point of the polymer. In preferred embodiments, the polymer is an ethylene-vinyl ester copolymer of the general formula . . ."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:65-4:39 ("In a presently preferred embodiment, the polymeric materials useful for forming the matrix are the ethylenevinyl ester copolymers of the general formula . . ."); col. 9:40-10:17; col. 10:18-32.

Schiraldi '243: Col. 1:58-60 ("Other polymers that might be added are vinyl copolymers, polysaccharides, gelatin and collagen."); col. 2:30-51; col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion

of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 3:14-34; col. 4:67-5:27; col. 10:3-7; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Helwing '868: Abstract ("The compositions may either be in capped form or leashed to a polymeric backbone. . . . The primary uses of the compositions are in controlled release applications such as drugs . . . or in any application where predictable hydrolytic release of the active agent is desirable."); col. 1:6-16 ("The present invention relates generally to compositions of matter and more particularly to covalently bonded compounds composed of active agents containing reactive functional groups The primary uses of the invention are in hydrolysable controlled release utilizations of active agents in such areas as pharmaceuticals, insecticides, herbicides, and the like."); col. 1:19-37 ("In addition . . . it may be highly desirable to have a system that permits the continuous controlled release of an agent . . ."); col. 1:38-2:11 ("One of the most common methods of achieving predictable controlled release mechanism of an active chemical agent is to encapsulate the agent with another material which gradually degrades in the desired medium. . . . A similar method is to trap molecules of the active agent within a surrounding polymer matrix. The matrix structure is such that exposure to an environmental material, usually water, causes the matrix structure to gradually degrade until the surrounding matrix structure is decomposed to the extent that the active agent molecule is permitted to escape into the environment. . . . The Heller, et al. patent utilizes a polymer structure . . . subject to hydrolysis, that is, it is subject to degradation in a gradual manner upon contact with water."); col. 2:12-24 ("The usefulness of structures such as that taught in Heller, et al. patent is significantly dependent upon the unique bioerodable, or hydrolysable, bonding structure . . ."); col. 2:25-37 ("The bonds so formed between the ketene acetals or vinyl ethers and hydroxyl groups are readily hydrolysable under even mildly acidic conditions. It is postulated that similar results will be obtained between various other functional groups on active agents and ketene acetals or vinyl ethers, and that these linkages will be hydrolysable with degradation of the covalent bond in the presence of water providing an ideal mechanism for controlled release of chemical or biological agents."); col. 38-53 ("In the present invention, as active agents will be bonded directly to the controlled release matrix, specific structural design of the base component system will most directly affect control over the hydrophobicity of the overall matrix."); col. 2:55-3:27; col. 3:37-43 ("It is an object of the present invention to provide an aggregation of useful chemical compounds wherein a chemically active agent via its polar active (PA) functional groups is covalently bonded with a carbonium ion mechanism ("CIM") base group, the bond therebetween being hydrolysable in a predictable manner, resulting in controlled release."); col. 3:47-50; col. 3:62-66; col.3:67-4:17 ("The present invention is an aggregation of compositions consisting of a hydrolysable covalent bond formed between a base structure and an active agent structure. . . . The combinations are particularly adapted for use in controlled release of the active agents by way of hydrolysis. The usefulness of the combinations of the present invention is found in a wide degree of chemical and biological applications including drugs . . ."); col. 4:18-38 ("The inventive compositions of matter have the common property that

the covalent bond joining the active agent to the base component is predictably hydrolyzable."); col. 4:39-5:6; col. 5:7-46; col. 5:47-50 ("An advantage of the present invention is that new compositions of matter may be created which are subject to predictable hydrolysis under selected environmental conditions."); col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20 ("Each of the compositions of the present invention has two distinct moieties joined by a hydrolyzable covalent bond. . . . The active component will have this chemical or biological effect when it is in its free molecular form but will not have the same effect when it is restricted in the inventive composition by the covalent bond. The hydrolytic decomposition of the covalent bond will act to release the agent so that it may again act in its original molecular form."); col. 7:21-8:50 ("Polymeric support substrates for the leashed systems would include polyvinyl alcohol, dextran, cellulose and similar polyhydroxy polymers."); col. 8:51-9:29 ("The common thread found in the various active agents is that each include one or more functional PA subgroups which are capable of forming the desired hydrolyzable covalent bond with the CIM subgroups of the base component in a predictable manner."); col. 9:30-52 ("With respect to other active agent functional PA groups and CIM base components, the bond structure will not be a pure orthoester linkage but will be of a similar hydrolyzable nature."); col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48 ("However, in the presence of water, the orthoester-type linkage is subject to hydrolysis as shown in equation EQ-2 and the Z group representing either the ketene acetal or thioacetal."); col. 12:49-13:5 ("The hydrophobicity of the inventive compositions may be altered such that the composition hydrolyzes at different rates."); col. 19:57 ("As is clear from the above, the scope of possible compositions that can be created according to the present invention is extremely broad. . . . All of the inventive compositions are such that they may be created by the process of the present invention and all will be similar in that the CIM and PA groups will form a hydrolyzable covalent bond which will act to keep the inventive composition intact under environmental conditions until hydrolysis occurs."); col. 20:18-37 ("Timed-release drugs for controlled introduction into the blood stream or other body tissues or cavities are well known, including compositions referred to as pro-drugs. The inventive compositions are extremely well adapted for use in this field. . . . Along these lines, the inventive systems could be used to deliver not only general drugs, but cancer drugs, hormones, vitamins, fungicides and even used as a more durable sunscreen."); col. 20:46-54; col. 20:55-68 ("The preferred embodiment of the present invention may also be applied to a surface as a film of uniform consistency for use in several areas of application. . . . The chemically linked nature of the controlled release matrix affords not only the ability to apply such films, but permits the most compact physical structuring possible in a controlled release matrix as well as an assured even distribution of the desired agent."); col. 21:27-41; col. 21:42-46 ("The composition of claim 1 wherein said covalent bond is predictably degradable via hydrolysis such that the active agent component may be released in a controlled release manner under selected environmental conditions."); col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3 ("The composition of claim 1 wherein the covalent bond is destructible via hydrolysis at a predictable reaction rate in a specified environment to yield a hydrolytically degraded base component and the active component as separate molecules."); col. 23:4-col. 24:27.

Valentini '029: Col. 3:15-25 ("The semipermeable nerve guidance channels of the present invention can also be biodegradable.").

Greco '135: Abstract; col. 1:19-26 ("This invention relates to methodology for the surface modification of surgical implants permitting the binding of drugs which, after implantation, are slowly released. More particularly, this invention relates to improved surgical implants having sustained, localized delivery of pharmacological agents such as extended antibiotic activity or reduced thrombogenicity, and methods for producing same."); col. 1:29-2:59 ("The surface modification of surgical implants by the adhesion of pharmacological agents for the purpose of minimizing infection and prosthesis rejection is well-known and has generated broad interest for some time. . . . The present Application is therefore an effort to further disclose and particularize this aspect of the invention, i.e., the development of the antibiotic bonded prosthesis utilizing an anionic surfactant and the oppositely charged drug, antibiotic or other agent or factor."); col. 3:8-19 ("An object of the present invention is to provide improved surfactant-modified implantable devices having a drug, including antibiotics, antithrombogenic agents, thrombolytic agents, disinfectants, etc., bound to the surface thereof. . . . Another object of the present invention is to provide an improved implantable device having a drug bound thereto of improved release times."); col. 3:22-27; col. 3:30-43; col. 4:2-39; col. 5:30-6:58 (disclosing process by which antibodies can be bound to thermoplastic substrates); col. 7:46-9:3; col. 9:10-12.

Bawa '279: Abstract; col. 1:16-36; col. 2:27-35 ("With the foregoing and other objects in view, the invention herein provides a sustained-release polymeric hydrogel dosage form useful for topical, systemic or transdermal administration of a medicinal agent comprising one or more polymerizable hydrophilic polymers, an ion-exchange resin, a cross-linking agent and optionally one or more hydrophobic polymers."); col. 2:39-46; col. 2:47-68 ("The preferred hydrophilic monomers are the hydroxyalkyl esters, specifically hydroxyethyl methacrylate (HEMA)."); col. 4:14-25; col. 6:40-44 ("The invention contemplates a variety of processes for preparing the sustained-release polymeric hydrogel dosage form whereby the medicinal agent is retained by the polymeric matrix and, upon tissue contact, is gradually released into the tissue."); col. 7:15-21; col. 8:1-6; col. 8:29-49; col. 8:54-55; col. 8:66-68; col. 11:42-54; col. 13:10-17; col. 13:26-14:14.

Aebischer '627: Col. 3:23-49 ("In addition, these polymeric materials have the capacity for sustained release of the embedded substance at a controlled rate."); col. 3:57-4:3 ("The polymeric insert includes pores having a molecular weight exclusion of from about 1 kD to about 1,000 kD, but preferably from about 25kD to about 100 kD. In one preferred embodiment, the polymeric insert includes a hydrophobic matrix such as ethylene-vinyl acetate copolymer."); col. 6:52-59 ("the insert may be composed of any biocompatible material having the desired pore size and being composed of materials which do not limit the activity of the substance embedded therein. . . . [H]ydrophobic matrices such as ethylene vinyl acetate are particularly useful."); col. 7:3-12 ("One way of providing the source of neurotransmitter include incorporating it into the polymeric insert. The encapsulating material provides a protective environment for substances such as neurotransmitters or cell growth factors embedded therein, while affording sustained release of the substance at a controlled rate therefrom."); col. 7:13-28; col. 7:29-56 ("The release rate may also be controlled by the amount of pure, impermeably polymeric material coating the effector substance-embedded insert; the more (or thicker the) coatings, the slower the release rate. Materials such as polyurethane or pure ethylene-vinyl acetate are particularly useful for this

purpose."); col. 10:31-34 ("To retard dopamine release, three coats of 10% EVAc were applied to each rod by repeated immersion . . ."); col. 14:29-32; col. 14:45-49; col. 14:57-58.

Wood '066: Abstract ("A controlled-release bandage containing therapeutic agents in a poly(vinyl alcohol) cryogel is disclosed. The bandage may include . . . hydrophobic particles to further insure controlled and constant release of therapeutic agents."); col. 2:56-66 ("Bandages comprising cryogel and therapeutic agents are used to provide a protective covering and to provide a controlled and uniform administration of therapeutic agents to sites of trauma such as wound, thermal or chemical burns, ulcers, lesions or surgical sites. Cryogel bandages may include . . . particles having hydrophobic properties, which absorb the therapeutic agent and release it in an uniform and controlled manner."); col. 3:47-4:36; col. 7:6-32 ("The release of therapeutic agents from the bandage has been found to be further controllable by including insoluble particles capable of adsorbing or forming salts with the therapeutic agent in the bandage. . . . Other examples of suitable insoluble particles include hydrophobic resins, silica, hydroxyl apatite and aluminum oxide."); col. 7:43-50; col. 8:55-56; col. 26:8-18 ("The bandage of claim 1 wherein the insoluble particles capable of adsorbing or forming salts with the therapeutic agent are a hydrophobic resin particles.").

Strecker '746: Abstract; col. 1:63-2:2; col. 2:21-32; col. 3:5-17 ("Another sensible advanced version is characterized in that medications in the lining are dissolved in the wrapping material or included in the form of beads."), ("It can be practical for there to be more or less openings in the wall of the lining next to the lumen than there are in the wall next to the inner surface of the vessel. The ratio can be exploited to prescribe the dosage of medication to the lumen or wall of the blood vessel."); col. 3:17-26 ("The wrapping material can also to advantage be biodegradable When the material is biodegradable, the medication will be released not by diffusing out of the vehicle but by escaping as the vehicle that the medication is dissolved in or that accommodates the beads that encapsulate the medication at its surface decomposes and by accordingly coming into contact with body fluids."); col. 3:27-33; col. 5:10-12; col. 5:38-41; col. 6:1-17; col. 6:35-38; col. 7:16-37 ("a lining impregnated with medication for delivery to a wall of said body lumen"); col. 7:48-65; col. 8:19-10:19; Figs. 7 & 8.

Lambert '246: Abstract ("The biologically active compound is, therefore, released only at the site where it is desired, i.e., where the prosthetic article is positioned."); col. 1:46-55 ("Release of heparin from intravascular catheters in quantities sufficient to decrease thrombosis on the catheter has been achieved by either covalently bonding a charged molecule to a polymer or incorporating a large nonmobile charged molecule on the surface of the polymer . . ."); col. 1:57-61; col. 2:15-34 ("Increasing the lipid solubility of the compound slows release from the polyurethane, and increases the tissue retention. More lipid soluble compounds are, therefore, preferred agents for use in the practice of the present invention."); col. 2:38-40 ("In accordance with the present invention, there is provided a method for preparing a system suitable for localized delivery of biologically active compounds to a subject."); col. 2:40-49; col. 2:53-65; col. 7:31-33 ("The results of this example demonstrate that polyurethane stent coatings can concentrate and release lipophilic drugs in vitro."); col. 8:58-9:4 ("Adventitia overlying the stent contained 360 times the concentration of forskolin in the blood and 305 times the concentration of forskolin in the contralateral artery. . . . In a similar model, etretinate, a retinoic acid analog, develops concentrations in the media of 250 ng/mg tissue at 24 hours. At 24 hours, this

concentration was over 2000 times the concentration in the blood."); col. 9:31-37 ("These data demonstrate that a polyurethane coated nitinol stent is capable of delivering a lipophilic drug in high local concentration in the vessel wall. The large 450 fold differential of local tissue levels of forskolin over blood levels reflects the capability of this delivery system to provide high local concentration and potentially higher efficacy, with lower risk of systemic side effects."); col. 10:47-50; col. 10:62-64 ("The drug delivery system of claim 1 wherein the biological agent is absorbed substantially throughout the entire thickness of the polyurethane elastomer coating."); col. 11:16-17 ("The drug delivery system of claim 8, wherein said biologically active compound is a lipophilic compound."); col. 11:30-31; col. 11:36-40; col. 12:12-13; col. 12:17-21; col. 12:53-54.

Bellamkonda '029: Col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 5:32-48 ("The agarose hydrogels of this invention may be used as a carrier to present various ECM proteins or peptides We prefer covalent immobilization of ECM proteins to the hydrogel backbone."); col. 7:26-32 ("In a preferred embodiment, laminin-derived oligopeptidic fragments . . . are coupled to the hydroxyl backbone of agarose, using any suitable method."); col. 9:36-48 ("These growth factors may be incorporated into the channel membrane . . ."); col. 11:7-8 ("Additionally, the membrane may be composed of a biodegradable material."); col. 11:41-50; col. 12:13-16 ("Preferably the permselective membrane is fabricated to be impermeable to some of these substances so that they are retained in the proximity of the regenerating nerve ends."); col. 12:42-49; col. 12:50-56; col. 15:67-16:17; col. 23:54-24:55.

Dayton '382: Abstract ("The stent is then coated with a polymer . . . which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids, with the equilibrium being controlled by charge distribution, concentration and molecular weight of the bioactive substance in relation to the pore size of the polymeric carrier for controlled prolonged release of said bioactive substance."); col. 1:9-17 ("The present invention relates to an improved percutaneously inserted endoprosthesis device which is permanently or temporarily implanted within a body vessel, typically a blood vessel. More particularly, the present invention relates to a new procedure for administering localized bioactive substances via prosthesis designs . . ."); col. 3:36-39; col. 3:62-4:17 ("Among these polymers are polymers having a microporous structure, such as . . . biodegradable polylactic acid polymers, polyglycolic acid polymers . . ."); col. 4:24-33 ("A bioactive substance is preferably admixed in the polymer for elution from the microporous structure of the stent or coating on the stent after implantation. The rate of elution of the bioactive substance is controlled by selecting a pore size for microporous structure . . ."); col. 6:64-7:7 ("Also included in the polymer is a bioactive substance having a charge distribution, concentration and molecular weight selected which achieves an equilibrium in relation to the pore size of the polymeric carrier with said surrounding body tissues or fluids."); col. 7:8-14; col. 7:20-23.

Burt '036: p.4:19-33 ("Within one aspect of the present invention, compositions are provided . . . comprising (a) an anti-angiogenic factor and (b) a polymeric carrier. A wide variety of molecules may be utilized within the scope of the present invention as anti-angiogenic factors Similarly a wide variety of polymeric carriers may be utilized, representative examples of which include poly(ethylene-vinyl acetate) . . . and copolymers of polylactic acid and polycaprolactone."); p.10:17-25; p.14:9-27; p.21:2-4; p.51:1-52:35.

Goldin '568: Abstract; col. 1:21-34 ("In certain circumstances, another desirable use of controlled release methods is to target the delivery of a therapeutic agent specifically to the tissue or site that can benefit from the presence of such an agent."); col. 1:35-41 ("Several classes of controlled release strategies have been developed, principally involving: (a) release by controlled diffusion; . . . and (c) release limited by chemical control of the interaction of the agent with a substrate to which it is adsorbed or bound."); col. 1:43-62 ("Release by controlled diffusion may be accomplished by means of containment of the therapeutic agent within a substrate whose small pore size and/or tortuosity of diffusion path thereof limits the diffusion of said agent through the substrate. . . . The therapeutic agent can be incorporated within the diffusion-limiting substrate Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:8-16 ("Towards that end, diffusion-controlled slow release devices have been fabricated from biodegradable polymers . . ."); col. 2:24-28; col. 3:42-53 ("Release by chemical control most commonly involves chemical cleavage from a substrate to which a therapeutic agent is immobilized, and/or by biodegradation of the polymer to which the agent is immobilized."); col. 3:54-65 ("Another variant of release by chemical control termed herein "controlled noncovalent dissociation or 'CND'", relates to release resulting from dissociation of an agent that is bound temporarily by non-covalent binding of the agent to a substrate."); col. 4:25-45 ("The microskin is specifically tailored to bind macromolecules . . . noncovalently by cooperative secondary bonds, and slowly release the macromolecules by controlled non-covalent dissociation (CND)"); col. 4:63-66; col. 6:1-19 ("Because preferred embodiments of the CND controlled Release Device and methods of use thereof employ membranes whose pore size is normally much greater than molecular dimensions, the kinetics of release are governed primarily by the strength and number of the reversible cooperative secondary bonds which immobilize said protein for CND."); col. 6:20-29 ("Limitation of the toxicity associated with the macromolecules to be released results from selective delivery to the site of action in the amounts and at the time needed. While in practice, the temporal and spatial selectivity of the current invention may not be absolute, it is clearly an improvement over more conventional modes of delivery . . ."); Fig. 1A; Fig. 1B; col. 8:65-9:6; col. 9:18-22; col. 9:23-30; col. 9:43-50 (" . . . delivery from controlled release devices can be controlled by diffusion out of said device, dissociation of chemical bonds, and the like."); col. 9:51-55; col. 10:45-54; col. 17:40-54 ("[S]ynthetic polymers . . . may be derivatized to attach functional groups which may react under appropriate circumstances to form covalent bonds with the macromolecules one wishes to bind and release in a controlled manner."); col. 20:9-12 ("By appropriate use of said Device, one can selectively target a therapeutic site . . ."); col. 20:46-21:19 ("[W]hen the pore size of the underlayment and/or the microskin approaches submicron dimensions and/or the thickness of said Devices approaches millimeter dimensions or greater, diffusion of the agent to be delivered out of said device may contribute to or even be the predominant process governing controlled release from said

Device."); col. 21:47-49 ("A coating of a permeable guide tube, with a secondary membrane designed to exclude macromolecules from without."); col. 27:10-18; col. 32:26-31.

Palmaz '762: Col. 10: 28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '337: Col. 9: 24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Zaffaroni '254: col. 2:6-9 ("Still another approach has been to enclose the drug within a single capsule having a polymeric wall or walls through which the drug can pass, for example, by diffusion."); col. 2:16-26 ("Additionally, these prior art devices have generally been based on the use of a single material, such as silicone rubber polymers, especially polydimethylsiloxane, as the diffusion control membrane. In large part, these polymers were selected because of their permeability to some important drug molecules. But, it has been found that mere high permeability without consideration of release rate controlling properties can be a significant disadvantage which defeats the primary object of an acceptable drug delivery device."); col. 4:54-58 ("In operation, solid drug carrier 13 serves as a reservoir 12 by supplying dissolved drug 14 to the micropores 15 of wall 11 as drug molecules move through the carrier to bathe the inner surface of wall 11."); col. 7:18-25.

Langer I: p.29 ("In the bioerodible system, the drug is distributed relatively uniformly throughout the plastic as in matrix systems, but it differs from the matrix in that its plastic portion decreases with time. As the plastic surrounding the drug is eroded, the drug escapes. . . . The most popular bioerodible polymers have been absorbable suture materials such as polylactic acid."); p.29-30 ("The second type of chemically controlled system is known as a pendant chain system. In simplest form, the drug is attached via chemical bonds to a polymer backbone. It could also be attached via a spacer group Release occurs when water reacts to break those bonds, thereby freeing the drug. Release rates are adjusted by varying the hydrophilicity of the polymer backbone. Systems could also be designed so that an enzymatic reaction could break the drug-polymer bonds."); p.29 Figure legend ("Chemically controlled pendant chain drug-delivery system. Here, the drug is bound to a polymer backbone and released by hyd[r]olytic or enzymatic cleavage, the key to controlling the medication's delivery.").

Langer II: p.217-18 ("In chemically controlled systems, release is accomplished either by biodegradation of the polymer . . . or by chemical cleavage of the drug from a polymer backbone to which the drug had been bound as a pendent group."); p.218 Fig. 3; p.219 Fig. 4 ("Chemically controlled pendent-chain drug-delivery system. Here, the drug is bound to a polymer backbone and released by hydrolytic or enzymatic cleavage."); p.221-225 ("Contraception" "Immunization" "Anticoagulation" "Cancer" "Insulin Delivery" "Controlled-release formulations may be applied to other clinical areas, including the release of narcotic antagonists, antibiotics, interferons, anesthetics, anti-arrhythmics, and antimalarial drugs.").

Langer III: p.25 ("Matrix Systems"); p.26-27 ("From a chemical standpoint, Heller has considered bioerodible systems in terms of three dissolution mechanisms: [1] water-soluble polymers insolubilized by degradable cross-links; [2] water-insoluble polymers solubilized by hydrolysis, ionization, or protonation of pendant side-groups; and [3] water-soluble molecules. These mechanisms represent extreme cases, and erosion by a combination of mechanisms is possible."); Fig. 3-3; Fig. 3-4; p.27-28 ("In pendant chain systems, a drug is chemically bound to a polymer backbone-chain and is released by hydrolytic or enzymatic cleavage. . . . The polymer system can be either soluble or insoluble . . . insoluble forms are more desirable for long-term controlled-release implants. The backbone may also be biodegradable or nonbiodegradable. . . . The drug itself can be attached directly to the polymer or attached via a spacer group. The spacer group may be used to affect the rate of release and hydrophilicity of the system.").

Langer & Peppas: Fig. 5; p.80-83 ("Matrix Systems"); p.83 ("Polymers for Diffusion-Controlled Systems"); p.84; p.85 ("Ethylene-vinyl acetate (EVA) copolymers have found major applications in controlled release of bioactive agents because of their relatively good chemical stability, biocompatibility, and inertness."); Fig. 7; p.86-87 ("Chemically controlled drug release generally involves one of two types of systems: 1) Erodible systems in which the drug is dispersed in a biodegradable polymer and drug release is influenced by the rate of degradation of the polymeric material, and 2) pendant chain systems in which the drug is attached to a polymer through a hydrolytically or enzymatically labile linkage. Drug release is influenced by the rate of degradation of this linkage."); Fig. 8; p.87-100 (describing and identifying polymers for biodegradable drug release systems); p.100-101 ("In [pendant chain systems] a drug is chemically bound to a polymer backbone and is released by hydrolytic or enzymatic cleavage. . . . [I]nsoluble [backbones] are more desirable for long-term controlled-release implants. . . . The drug itself can be attached directly to the polymer or it can be attached via a spacer group. The spacer group may be used to affect the rate of release and hydrophilicity of the system. To achieve near constant release, the cleavage of the drug from the polymer must be the rate-limiting step. . . . There has recently been interest in developing controlled-release systems using pendant chain polymers for clinical applications."); p.114-16 ("Medical applications of controlled-release systems can be divided into four general areas: oral systems, transdermal systems, external implants, and subcutaneous implants.").

Langer IV: p.36 ("In matrix systems, the drug is uniformly distributed through a polymer."); Fig. 2; p.37 ("Two systems of chemical control exist. The first mechanism is bioerosion or biodegradation of the polymer. As the polymer surrounding the drug is eroded, the drug escapes. . . . The second type of chemically controlled system is known as a pendant chain system. In simplest form, the drug is attached via chemical bonds to a polymer backbone. It could also be attached via a spacer group. Release rates are adjusted by varying the hydrophilicity of the polymer backbone. Systems could also be designed so that an enzymatic reaction could break the drug-polymer bonds."); p.37 Fig. 3 ("Idealized diagram of the cross-section of a cylindrical or spherical bioerodible matrix."); p.37 Fig. 4 ("Idealized diagram of a chemically controlled pendant chain drug delivery system. The drug could be connected to the polymer backbone as shown or could be coupled to a spacer group attached to the polymer backbone."); p.41-42 ("The second type of [contraceptive] system is a subdermal implant composed of a biodegradable polymer."); p.44 ("Small (0.3 mm³) injectable pellets of ethylene-

vinyl acetate copolymer containing 100 ug of a test antigen, bovine serum albumin, were positioned subcutaneously in mice.").

Langer V: p.24 (" Examples of polymers with these properties include nondegradable polymers such as ethylene-vinyl acetate copolymers (EVAc), and biodegradable polymers such as polylactic or polyglycolic acid.") ("Theoretically, the [biodegradable] polymers should have a hydrophobic backbone, but with water-labile linkage.").

Langer VI: p.115 (One approach that has received increasing attention as a means of prolonging drug release has been the incorporation of drugs in solid polymers (e.g., silicone rubber, ethylene-vinylacetate copolymer). This method permits drugs to be released for long time periods in a controlled fashion."); p.120-124 ("The ideal [biodegradable] polymer would have a hydrophobic backbone, but with water labile linkage.").

Laurencin & Langer: Fig. 2; p.304-306 ("Matrix Systems"); p.306-307 ("Three dissolution mechanisms for bioerodible polymeric devices are found in general: Type 1: water soluble polymers that are made insoluble through crosslinks that are degradable. On exposure to an aqueous environment, crosslinks are broken, polymer dissolves, and release occurs. Type 2: water insoluble polymers that on exposure to an aqueous environment are solubilized by hydrolysis, ionization, or protonation of pendant side groups. Type 3: water insoluble polymers containing hydrolytically unstable backbone linkages. On exposure to an aqueous environment, polymer chains are cleaved to small water soluble monomers."); p.307 Fig. 4; p.308-309 ("In [pendant chain systems], drug is chemically bound to the backbone of a polymer. Release takes place by hydrolytic or enzymatic cleavage. . . . Polymer systems can be soluble or insoluble, and the backbone itself may be bioerodible or nonbioerodible. Soluble backbone chains are generally used for transport functions such as cell targeting; insoluble forms are more desirable for long-term controlled release implants. Drug can be chemically attached to the polymer directly or through a spacer group. The spacer group may be used to affect the rate of release or hydrophilicity of the system."); p.308 Fig. 5 ("Chemically controlled pendant chain drug delivery device. Drug bound to polymer backbone is released by hydrolytic or enzymatic cleavage."); p.313-316 (clinical applications of EVAc and biodegradable polymers).

Langer VII: p.1529 ("Chemical control is accomplished either by polymer degradation or chemical cleavage of the drug from a polymer."); p.1529 Fig.1(B), (C) and (D); p.1530 ("Examples of polymers that perform in this way are non-degradable ethylene-vinyl acetate copolymer and degradable lactic acid-glycolic acid copolymers."); p.1531-32 ("Theoretically, the [ideal surface-eroding] polymer should be hydrophobic but should have water-labile linkages.").

Langer & Moses: p.341-42 ("[W]e proposed that an ideal polymer would have a hydrophobic backbone, but with a water labile linkage."); p.342-44 ("One such report . . . employed the porous ethylene-vinyl acetate copolymer (EVAc) system to provide sustained release of fibroblast growth factor (FGF) or epidermal growth factor (EGF).").

Chien: p.32-33 ("[The hydrolysis-activated] controlled drug delivery system depends on the hydrolysis process to activate the release of drug molecules. . . . The release of a drug from the polymer matrix is activated by the hydrolysis-induced degradation of polymer chains and controlled by the rate of polymer degradation.") ("[The enzyme-activated] controlled drug

delivery system depends on the enzymatic process to activate the release of drug. . . . The release of drugs is activated by the enzymatic hydrolysis of the biopolymers by a specific enzyme in the target tissue."); p.37 ("An ideal site-targeting drug delivery system has been proposed . . . constructed from a nonimmunogenic and biodegradable polymer backbone having . . . a drug moiety that is covalently [sic] bonded to the polymer backbone through a spacer and contains a cleavable [sic] group that can be cleaved only by a specific enzyme(s) at the target tissue.").

Thomson: p.34-36 ("The degradation of synthetic polymers is, in general, brought about by simple hydrolysis, although in some cases enzymatic processes assist in the degradation mechanism.").

Hanes & Langer: p. 647 ("Polymers can also be used to deliver vaccines in a controlled manner."); p.648 ("Biodegradable polymeric devices or pendant chain systems are examples of chemically controlled devices. In the former, molecules are typically dissolved or entrapped in a biodegradable, bioresorbable polymer matrix As the polymer degrades and erodes, molecules are released to the surroundings. In pendant chain systems, molecules are chemically attached to the backbone of a polymeric carrier using hydrolytically or enzymatically degradable bonds. In this case, the molecules are liberated as the bonds holding them to the polymer are cleaved."); p.649 Fig. 29.2; p. 652 ("For the present development of vaccine delivery systems, the use of biodegradable polymers presents significant advantages over the use of nondegradable systems."); p.654-55 ("There are many such polymers that may prove useful for controlled delivery of vaccines; however, no degradable polymer systems has been more widely studied with respect to release kinetics than the lactide/glycolide polyesters."); p.655-56; p.656-58 ("Advantages of Controlled Release for Immunization").

Batz: p.26-27 ("Based on their chemical structure polymeric drugs are divided into the following three groups b) Drugs in which the active substance of known biological activity is bound to a polymeric carrier molecule via a functional group."); p.36-43 ("Polymeric drugs formed by covalent bond of known active components to soluble macromolecular carriers"); p.48 ("Polymeric Forms of Deposit Without Covalent Bond Between Drugs and Polymeric Materials.").

Donaruma: p.10 ("Allan, Chopra, Neogi, and Wilkins, in studies concerned with the design and synthesis of controlled release pesticide polymer combinations, investigated the duration of effectiveness of various herbicidal phenoxyacetic acids chemically bound as pendant substitutes to natural or synthetic water-soluble and water-insoluble polymers."); p.17, 19-20 ("[I]t can be seen that in some cases portions of the polymer repeat unit are structurally constituted so that by hydrolysis the polymer chain or a pendant group may be sundered by hydrolysis. . . . Chemically combining a drug in a polymer may offer a means of sustained release and/or prolonged activity of drugs and/or drug latentiation. These are not new concepts, and examples are reported in the literature.").

Harris I: p.334 ("As reported in this review, our work has involved the syntheses and evaluation of polymers containing pendant aquatic herbicides."); p.344 ("The herbicide release rates of polymers containing herbicides as pendant substituents are extremely slow in water with

pH=C at 30°C. The herbicide release rates, however, can be increased by incorporating hydrophilic groups along the polymers' backbones").

Feld: p.113-15 ("One approach to obtaining these formulations has been the synthesis of polymers that contain pesticides as pendent side chains. . . . Pesticide release occurs by the slow, sequential hydrolysis of the pesticide-polymer chemical bonds. This provides a sustained release of the pesticide over an extended period of time. The actual release depends on the nature of the pesticide polymer bond and the dimensions and structure of the resultant macromolecular combination."); p.116-17 ("It was postulated that increasing the length of the pendent side chain would enhance the hydrolysis of the herbicide-polymer bond."); 117-19 ("Herbicide reactivation was produced enzymatically using lipase, acetylcholinesterase and trypsin.").

Harris & Post I: p.622 ("One approach to obtaining controlled-release pesticide formulations that contain a high percentage of pesticide has been the synthesis of polymers that contain pesticides as pendent side chains. The pesticide is presumably released by the slow sequential hydrolysis of the pesticide-polymer chemical bonds. . . . It was postulated that increasing the length of the pendent side chain would enhance the hydrolysis of the herbicide-polymer bond.").

Harris & Post II: p.225 ("One approach to obtaining controlled-release pesticide formulations that contain a high percentage of pesticide has been the synthesis of polymers that contain pesticides as pendent side chains. The pesticide is presumably released by the slow sequential hydrolysis of the pesticide-polymer chemical bonds. . . . It was postulated that increasing the length of the pendent side chain would enhance the hydrolysis of the herbicide-polymer bond.").

Drobnik: p.2833 ("Water-soluble copolymers based on poly[N-(2-hydroxypropyl)methacrylamide] and bearing in their side chains a chromogenic substrate for chymotrypsin were prepared by direct copolymerization or polymeranalogous reaction."); p.2834 ("The bonding of drugs onto macromolecules is an old idea, because it offers a potential optimization of the pharmacokinetics of drugs. The majority of pharmaceuticals are inactive in the macromolecular form and must, therefore, be released in their original active low-molecular weight form, i.e. their attachment to the polymer must be reversible, or degradable."); p.2844-47 ("The results also indicate the general influence of the spacer: the longer the spacer, the easier the cleavage of the enzyme susceptibility bound For practical purposes, that is, enzyme-specific binding of drugs to polymers, the following conclusions can be drawn from the above results . . .").

Allan I: p.17 ("These materials are chemical or physical combinations of known and established pesticides with macromolecules. . . . As the pesticide-polymer combination lies in the soil, a gradual decomposition occurs, and the pesticide is slowly released over the desired and predictable period of time."); p.18-19 ("This situation is avoided by the use of a chemical combination of the butyric acid [herbicide] with the polymeric components of bark. The ester linkage joining the herbicide to the bark will not be easily attacked by any β -oxidase and the butyric acid herbicide is thereby stabilized. Essentially, the only butyric acid herbicide available for β -oxidation is that continuously being released from the bark. This release will occur

whether the combination lies in or on the surface of the soil since attack by moisture, micro-organisms and the weather can occur in either of these zones.").

Allan II: p.349 ("We have therefore investigated the potential of pesticide-polymer combinations as a means of securing controlled release of a biodegradable pesticide in approximately the correct amount needed over an appropriate period of time. . . . Two distinct approaches are not reported. (a) Pesticide release by diffusion through polymers, and (b) pesticide release by degradation of a polymer containing the pesticide as a pendent side chain. . . . For case (b) the pesticides . . . are chemically attached as a pendent substituent to a natural or synthetic water-soluble or insoluble polymer . . ."); p.350 ("In the biological environment, side chain degradation occurs so that the chemical bonds holding the pesticide within its polymeric prison are sequentially broken to provide a sustained release of the pesticide over an extended period of time. The rate of release will clearly be determined by the nature of the pesticide-polymer bonds, the chemical characteristics of the pesticide and polymer and the dimensions and structure of the resultant macromolecular combination.") ("Although developed for developed for forest pest control the systems described should be broadly applicable to the controlled release of other biologically active substances.").

Allan III: p.173: ("Controlled release from polymeric matrix"); p.173-74 ("Representative of the other end of the thermodynamic spectrum is the situation where the pesticide is firmly attached to the substrate by a high energy covalent bond. Release of the pesticide then involves the cleavage of a definite identifiable chemical bond such as an ester or amide. . . . The simplest [arrangement] has the pesticide attached as a pendent substituent to a natural or synthetic water-soluble or insoluble polymer having a replaceable hydrogen The chemical bonds holding the pesticide within its polymeric prison are sequentially broken to provide a sustained liberation of the pesticide over an extended period of time."); p. 176 ("Moreover, the [controlled release] concept is broadly applicable to the release of other biologically active substances.").

Jakubke: p. 281 ("Observations in our laboratory indicated that an enzymatic cleavage of carrier-bound biologically active substance of low molecular weight is fundamentally possible. As part of a general model study of enzymatic reactions with insoluble substrates we investigated the α -chymotrypsin-catalyzed hydrolysis of Sepharose-bound L-phenylalanine 4-nitroanilide. As a spacer, 1 or 2 mol of 6-amino-hexanoic acid, respectively, were inserted between the gel matrix and the low-molecular weight substrate."); p. 282 ("The course of hydrolysis was proportional to time during the first 15 min. About 70% of total bound (ϵ Ahx)₂-Phe-NA was hydrolyzed after 4 hr."); Fig. 2 ("Dependence of hydrolysis on the enzyme concentration at 25°C."); p. 283 ("In agreement with this the substrate dependence of the hydrolysis rate shows the same course as observed with Glt-Phe-NA.").

Engelberg & Kohn: p. 292 ("For example, degradable polymers are now being investigated as intra-luminal grafts, stent-like devices that are implanted into coronary arteries in an attempt to prevent the collapse and the reblocking (restenosis) of blood vessels after successful balloon angioplasty."); p.293 ("Since surface-eroding, slab-like devices tend to release drugs embedded within the polymer at a constant rate, poly(ortho esters) appear to be particularly useful for controlled release drug delivery. It is not surprising that there are a

significant number of publications describing the use of poly(ortho esters) for drug delivery applications."); p. 293-94 ("PLA, PGA and their copolymers are also being intensively investigated for a large number of drug-delivery applications. . . . PLA, PGA and their copolymers are currently the most widely used synthetic degradable polymers in human medicine."); p.294, Table 1; 294-95 (The potential applications of these [PHB polymers] include biomedical applications such as controlled drug release . . ."); p.295 ("Later, it was discovered that PCL can also be degraded by a hydrolytic mechanism under physiological conditions. Under certain circumstances, cross-linked PCL can be degraded enzymatically, leading to enzymatic surface erosion."); p.296 ("It is interesting to note that despite its versatility, PCL has so far been predominantly considered for controlled-release drug-delivery applications.") ("The low hydrolytic stability] was later recognized as a potential advantage by Langer et al. who suggested the use of polyanhydrides as degradable biomaterials."); p. 297; p. 298 ("Poly(ortho esters)"); p. 298-99 ("PGA"); p. 299 ("PLA"); p. 300 ("PBH and copolymers with HV"); p. 301 ("PCL") ("Because of their low mechanical strength and high hydrolytic reactivity, the two polyanhydrides tested appear to be limited to drug-delivery applications."); p. 302.

Roseman & Mansdorf: p. 91-105 ("The objective of this chapter is to describe the development of a bioerodible polymer implant that would release an incorporated drug by zero-order kinetics for at least 6 months. A further objective is the development of a system where drug release and polymer erosion take place concomitantly so that no polymer remains when the drug is depleted."); p. 107 ("There have been, however, studies where polymer-drug complexes have been synthesized, the major objective of which was to provide a controlled or prolonged action of the drug by the natural hydrolysis or biological scission of the covalent polymer-drug bond. In this way, mescaline, insulin, salicylic acid, D-isoproterenol, naloxone, plant cytokinins, 2,4-dichlorophenoxyacetic acid, norethindrone, and cortisol-21-acetate have been attached to and released from various synthetic and natural polymers through covalent bonds such as amide, ester, aso, carbamate, carbonate, oxime ester, and hydrazone."); p. 108 ("GAGs are biodegradable by enzymatic means normal to the host."); 108-109 ("We have taken advantage of various types of functional groups available on the GAG backbone (carboxyl, primary and secondary hydroxyl, and sulfate) in preparing and testing a series of complexes in which the drug was bound directly to the polymer or via an intermediate linking group such as an amino acid or other such bioacceptable entity. . . . Current work with other drugs bound to the GAG backbone by the same and different bond types (i.e., carbamate, ionic) will be reported in the near future."); p.110; p. 111 ("Amide and ester bond types were chosen because both are susceptible to chemical hydrolysis and both are prevalent naturally and thus are potentially dependable by enzymes."); p. 112 Fig. 2 & 3; p. 112-113 ("The release was pseudo-first order with a release rate constant of 0.10 day^{-1} and a half-life of 3.8 days. This is what one would expect if the rate-determining stem for release is the chemical hydrolysis of the ester bond in the prodrug."); p. 113 ("Reactions on polymers, such as the hydrolytic cleavage of GAG-drug bonds, has been shown to be affected by polymer chain length and conformation, steric isolation, and neighboring group effects."); p. 114; p. 115 ("Even though the amid bond between the drug and the polymer may hydrolyze slowly over this period and release cysteine, the rate-determining step for release was probably enzymatic breakdown of the complex. . . . A large advantage of using glycosaminoglycans as drug carriers is that they are biocompatible and biodegradable."); p.116 ("Chloramphenicol-GAG ester complexes released Cpl quickly by scission of the ester bon. Cysteine-GAG amide complexes degraded much more slowly and probably through

enzymatic hydrolysis of the polymer or polymer-drug bond."); p. 117 ("Nevertheless, this concept provides an interesting base from which to design a drug release system; the rate of release may in principle be engineered by the judicious choice of drug-GAG bond based on the hydrolytic stability of the bond.").

Lee & Good: p. 2; p. 2-3 ("As a result of research on improved absorbable sutures, poly (lactic acid), poly (glycolic acid), and lactic/glycolic acid copolymers, which hydrolyze to natural metabolites, have been developed for drug delivery purposes."); p. 3 ("[P]olymer erosion can be controlled by the following three types of mechanisms: (1) water-soluble polymers insolubilized by hydrolytically unstable cross-links; (2) water-insoluble polymers solubilized by hydrolysis, ionization, or protonation of pendant groups; (2) hydrophobic polymers solubilized by backbone cleavage to small water soluble molecules. . . . [O]ther commonly used bioerodible/biodegradable polymers include polyorthoesters, polycaprolactone, polyaminoacids, polyanhydrides, and half esters of methyl vinyl ether-maleic anhydride copolymers.") ("Drug-Polymer conjugates. This system involve drug molecules chemically bounded to a polymer backbone. The drug will be released through hydrolytic or enzymatic cleavage. . . . The attachment of drugs to macromolecular carriers alters their rate of excretion from the body and provides the possibility for controlled release over a prolonged period. . . . Both natural polymers such as polysaccharides and synthetic polymers such as polylysine, polyglutamic acid, polyphosphazenes, copolymers of vinylpyrrolidone, copolymers of 2-hydroxypropylmethacrylamide, and etc. have been used as drug carriers."); p. 4 ("The drug-polymer linkage may be covalent, ionic, or through some weaker secondary molecular forces. The drug may be part of the polymeric backbone or attached to the side-chain either directly or through a spacer group. The spacer groups is generally selected in such a way that it may be hydrolyzed or degraded enzymatically under specific environmental conditions. Examples of such drug-polymer conjugates include the attachment of ampicillin, 6-amino-methacrylamide copolymers, methotrexate to poly (L-lysine), and norethindrone to poly(hydroxyalkyl)-L-glutamine. In addition to diffusion rate limitations as described in the next section, the drug release rate is primarily governed by the rate of cleavage of the drug from the polymer."); p.5- 7 ("Matrix Diffusion"); p. 7 ("Polymer Erosion. The release of a dissolved or dispersed drug from an erodible polymer matrix can be controlled by a variety of mechanisms ranging from hydrolysis/enzymatic cleavage as discussed in the previous section to swelling and dissolution."); p. 17 ("An important example of these processes is the controlled release of bioactive molecules from polymeric membranes. Many pharmaceutically active agents have been released at controlled rates from hydrophobic polymer carriers. . . . In 1976 it was demonstrated that hydrophobic polymers, in particular ethylene-vinyl acetate copolymer (EVAc), could be used to release molecules with molecular weights greater than 1000."); p. 182 ("Enzyme-Degradable Hydrogel"); p.188-200; p. 214-230.

Langer & Folkman I: p. 179 ("Therefore, we turned to other polymers such as ethylene-vinyl acetate copolymer . . ."); p. 180-83; p. 183-84 ("Poly(vinylalcohol), Hydron, and ethylene-vinyl acetate copolymer were examined for their ability to release soybean trypsin inhibitor . . ."); p. 185-88; col. 188-191 ("The following three studies demonstrate that the pellets are releasing macromolecules in biologically active form."); p. 191-92 ("The present experiments show that macromolecules with a wide range of molecular weights can be delivered in significant quantities from polymeric vehicles that are not inflammatory when implanted in

animals. These polymers can release macromolecules in biochemically and biologically active form for periods in excess of 100 days as measured by direct assays. . . . The eventual clinical application of these polymers for delivery of macromolecules such as insulin, heparin, or enzymes may merit consideration.").

Langer & Folkman II: p. 798-99 ("Polyvinylalcohol, Hydron and ethylene-vinyl acetate copolymer were examined for the ability to release soybean trypsin inhibitor . . .") ("These studies show that sustained release of proteins and other macromolecules from polymeric vehicles can be achieved over prolonged periods.").

Langer VIII: p. 1 ("One approach that has received increasing attention as a means of prolonging drug release has been the incorporation of drugs in solid polymers (e.g. silicone rubber, ethylene-vinyl acetate copolymer). This method permits drugs to be released for long time periods in a *controlled* fashion."); p. 10 ("Controlled-release polymer formulations may also find applications in other clinical areas. One such area that has received increasing attention is the controlled release of antibiotics. . . . Polymers have also been used to deliver anesthetics, anti-malarial drugs, anticoagulants, and drugs to combat cardiac arrhythmia."); p. 27 ("However, several recent studies have demonstrated that matrix systems can be engineered to permit continuous release of large molecules. By solvent casting normally impermeable polymers such as ethylene-vinyl acetate copolymer in volatile solvents . . . along with powdered macromolecule, a series of interconnecting channels is formed within the polymer matrix. . . . These macromolecular delivery systems now open the possibility of delivering many important large molecular weight compounds such as insulin or interferon for prolonged periods."); Fig. 20; p. 28-29 ("[T]he volume of bioerodible systems becomes smaller with time, and, as the polymer surrounding the drug is eroded, the drug escapes."); p. 30 ("Erosion could be caused by hydrolytic or enzymatic cleavage of the crosslinks so that the ultimate degradation products are high molecular weight polymers. Alternatively, the degradation could occur in the polymer backbone so that the degradation products have low molecular weights."); p. 31-32 ("The third category of biodegradable systems are water-insoluble polymers that undergo hydrolytic or enzymatic backbone cleavage and are solubilized to small water-soluble molecules. . . . The best example of this class of polymer is polylactic acid or copolymers of lactic acid and glycolic acid."); p. 32 ("Sidman and coworkers . . . developed a peptide copolymer of glutamic acid and ethyl-L-glutamate."); p. 32-34 ("Pendant Chain Systems: In this type of system, a drug is chemically bound to a polymer backbone and is released by hydrolytic or enzymatic cleavage. The use of these therapeutic agents has received considerable attention in drug-related research. The major thrust so far has been the design of polymer-drug complexes for short-term use that can reduce toxicity, increase therapeutic efficiency, or be targeted towards specific cells or organs. . . . The drug itself can be attached directly to the polymer or it can be attached via a spacer group. The spacer group may be used to affect the rate of release and the hydrophilicity of the system. . . . To achieve near constant release, the cleavage of the drug from the polymer must be the rate-limiting step."); Fig. 22.

Langer & Folkman III: p. 114-15; p.117-18 ("Demonstration of Long-term Release") ("In initial trials with soybean trypsin inhibitor . . . protein was released . . . least rapidly from ethylene-vinylacetate copolymer."); p. 119-20 ("When tested in this fashion, ethylene-vinylacetate copolymer pellets continued to produce zones on these slides for over 100 days,

indicating that the pellets were releasing nearly 1 ug/day or biochemically active protein."); p. 123-25 ("Insulin Delivery"); p. 125-26 ("Immunization Procedures").

Rhine: p. 265 ("Matrixes composed of ethylene-vinyl acetate copolymers are useful vehicles for the sustained release of macromolecules such as proteins These polymer systems had uniform drug distribution, and their release kinetics were reproducible."); p. 267 ("Therefore, macromolecules were added to a solution of polymer dissolved in a volatile solvent (methylene chloride). This mixture, when case and dried, produced matrixes capable of sustained macromolecular release. . . . The reproducibility of release kinetics for matrixes prepared by low temperature methods was demonstrated for different proteins and for a range of particle sizes and loadings."); p. 268 ("A coating can also be used to control macromolecular release kinetics."); p. 269 ("Clinically, these systems may prove valuable as single-step methods for immunization or for the continuous delivery of insulin and other high molecular weight drugs.").

Aebischer: p. 282-83 ("Chemically inert polymer matrices, allowing controlled release of entrapped macromolecules over long time periods . . . open a new avenue of investigation. . . . The solvents used appear to have no detrimental effects on the biological activity of a number of growth factors."); p. 283 ("Channel Fabrication"); p. 283 (disclosing the use of an impermeable outer coating which results in directional release of the treating factors into the lumen of the device); Table 1; p.286 ("The present study demonstrates that ethylene vinyl acetate copolymer can be fabricated into tubes with adequate physical properties for nerve entubulation and allows the controlled release of macromolecules.").

Langer IX: p.267 ("Two polymers suitable for sustained macromolecular release, poly(hydroxyethyl methacrylate), and alcohol-washed ethylene-vinyl acetate copolymer, were noninflammatory.") ("[W]e provide documentation that two polymers suitable for sustained macromolecular release, poly(hydroxyethyl methacrylate) (polyHEMA) and alcohol-washed ethylene-vinyl acetate copolymer, possess a high degree of biocompatibility in the rabbit cornea."); p.269; Table 1; p.276.

Langer X: p.179-80 ("Although we investigated several polymeric systems, the best results from the standpoint of tissue biocompatibility and long-term release (>100 days) were obtained with ethylene-vinyl acetate copolymer."); p.180 ("Biocompatibility studies"); p.181-87 ("In vitro and in vivo release kinetics"); p.192 ("Possible mechanisms of release of macromolecules") ("The absence of effect of ionic strength (fig7) suggests that osmotic pressure or charge interactions of drug with polymer have negligible roles in affecting release rates."); p. 195-200 ("Here, four studies exploring biomedical uses of these polymer systems are discussed. These include: (1) insulin delivery systems, (2) vehicles for immunization, (3) interferon delivery systems, and (4) systems for delivering anticancer or antiangiogenic macromolecules.").

Langer XI: p.95-96 ("Recent studies in our laboratory have demonstrated, however, that solvent casting of a variety of polymeric materials (ethylene-vinyl acetate copolymer, polyvinylalcohol, poly-2-hydroxymethyl-methacrylate) in the presence of powdered drug permits continuous release of macromolecules for over 100 days.").

Brown: p.1181 ("Macromolecules such as enzymes, antigens, and insulin have been released in biologically active form [from ethylene-vinyl acetate copolymers] for up to 6 months *in vivo*."); p. 1184 ("These data show that *in vivo* release can be accounted for by the same mechanisms operating *in vitro*; this should now make possible the further development and increased use of ethylene-vinyl acetate copolymer drug delivery systems.").

Kost & Langer: p.47-48 ("Bioerodible controlled systems."); p.48-49 ("Applications").

Hsu & Langer: p. 445-46 ("The current study shows the MW of EVAc copolymer is as important as drug loading and drug particle size in affecting the drug release kinetics. A release mechanism, which includes the properties of the polymer carrier, is proposed to serve as a guideline in selecting a suitable EVAc polymer carrier for a particular drug release device."); p.459.

Bawa: p.259 ("For example, EVAc polymers have been used as . . . delivery systems for insulin, interferon, and antigens."); p.263 ("Minimal effects exist due to osmosis or charge interaction of the drug with the polymer."); p.266 ("The data should be useful in the design of release vehicles for various polypeptides, polysaccharides, and other bioactive agents now produced by genetic engineering.").

Leong & Langer: p.202; p.203 ("The two common chemically controlled systems are a biodegradable matrix in which the drug is dispersed, and a polymer-drug conjugate in which the drug molecules are linked to the side chains of the polymer."); p.206-209 (describing use of biodegradable polymers for contraceptive systems); p.210-11 ("Against Ehrlich ascites carcinoma in rats, a sustained release of 5-fluorouracil from poly(ethylenevinylalcohol) is more efficacious than free drug administration."); p.211-14 ("Pendant systems"); p. 214-15 (use of EVAc for hormonal therapy and angiogenesis inhibition); 219-23 ("The clear demonstration of the feasibility [of sustained release of insulin from polymer] was later provided by a study using poly(ethylenevinylacetate) (EVAc).").

Baker: p.14-15 ("Diffusion-Controlled Monolithic Systems"); p.15-16 ("Biodegradable Systems"); 161-65 ("Poly(ethylene vinyl acetate)").

Langer XII: p.162 ("In chemically controlled systems, release is accomplished either by biodegradation of the polymer or by chemical cleavage of the drug from a polymer backbone on which the drug had been bound as a pendent group."); p.163 ("A variety of reservoir and matrix devices are prepared from swollen crosslinked hydrophilic polymers (hydrogels). Most successful devices of this kind are based on poly (2-hydroxyethyl methacrylate) (PHEMA) and related polymers although hydrophilic homopolymers of (poly vinyl 1-2-purrolidone) (PNVP), poly (vinyl alcohol) (PVA) and copolymers thereof have been tested with considerable success.") ("Ethylene-vinyl acetate (EVA) copolymers are prepared by emulsion copolymerization of ethylene and vinyl acetate. They are soluble in organic solvents and they can be used to prepare films or rods of dimensional stability and good mechanical strength."); p. 163-64 ("Biodegradable Polymers"); 164-67 (clinical uses for controlled-release polymer systems).

Langer XIII: p.166; p.170 ("Studies have also been conducted to explore numerous applications of these systems. These include release of insulin . . . , anti-calcification agents . . . , interferons . . . , growth factors . . . and inhibitors . . . , and neurologically active agents.").

Chasin: p.43-44 ("In designing a biodegradable system that would erode in a controlled heterogeneous manner without requiring any additives, we have suggested that due to the high liability of the anhydride linkage, polyanhydrides may be promising candidates."); p.45 ("Molding procedures"); p.47-62 ("Kinetics of Drug Release") (describing release of various compounds); p.66-68 (polyanhydride safety and clinical studies).

Langer XIV: p.538-40 (describing polymers used in controlled release systems, including cellulose, poly(glycolic acid) and poly(lactic acid), poly(ortho esters), polyanhydrides, silicone rubber, ethylene-vinyl acetate copolymer, and poly(2-hydroxyethyl methacrylate)); 540-42 (describing clinical uses for controlled release systems).

Brem: p.2 ("The ethylene-vinyl acetate copolymer (EVAc) is an example of a non-biodegradable polymer while poly[bis(p-carboxyphenoxy) propane-sebacic acid] copolymer (PCPP-SA) and the fatty acid dimmer-sebacic acid copolymer (FAD-SA) are examples of biodegradable polymers."); p.3 ("Clinical applications for the EVAc polymer include drug delivery for contraception, insulin therapy, cancer chemotherapy, glaucoma treatment, dental caries prevention, and asthma therapy."); p.4-6 (describing in vivo and clinical studies of PCPP-SA and EVAc based delivery of chemotherapeutic drugs).

Langer XV: p.102 ("Our best long-term release results were obtained with relatively hydrophobic polymers, such as ethylene-vinyl acetate co-polymer or lactic glycolic acid copolymer, using methylene chloride as a casting solvent."); p.105 ("Therefore, we proposed to initiate studies on the development of a new class of bioerodible polymers: polyanhydrides."); p.109 ("Through the NH₂ groups of lysine, specific amino acid sequences such as arginine-lysine-aspartic acid (RGD) have been chemically coupled to polylactic acid-co-lysine.").

Thompson: p.31-32; p.32 ("In this article, we include hydrolysis and enzymatic degradation under the heading of biodegradative processes."); p.32-33 ("Collagen is one of the most widely used and best characterized of the natural biomaterials"); p.33 ("Gelatin, cross-linked with formaldehyde, has been studied in vitro as a drug delivery matrix . . ."); p.33-34 ("Starch"); p.34 ("Furthermore, because of its hydrophilicity, cellulose has been utilized in pharmaceutical formulations to enhance water uptake and improve drug delivery.") ("The degradation of synthetic polymers is, in general, brought about by simply hydrolysis, although in some cases enzymatic processes assist in the degradation mechanism."); p.35 ("Since . . . the degradation characteristics of [poly(glycolic acid)] are predictable and reproducible, PGA has become a material of choice for many proposed applications calling for a synthetic biodegradable polymer.") ("Poly(L-lactic acid)"); p.36 ("Poly(ε-caprolactone)") ("[Poly(orthoesters)] have therefore been exploited as constant rate drug delivery devices.") ("Poly(anhydrides)"); p.36-41 ("Hydrophobic polymers") ("Poly(ethylene)"); p.41-44 ("Hydrophilic Polymers") ("Poly(2-hydroxyethyl methacrylate)"); p.44 ("Natural and synthetic biodegradable polymers have been utilized in drug delivery and tissue engineering. Drug

delivery systems based on biodegradable polymers facilitate the controlled release of drugs with the concurrent degradation of the polymer.").

Chandrasekaran: p.587 ("The simplest to a bioerodible drug delivery system is to disperse or dissolve the drug in a water-soluble polymer, which will slowly erode in an aqueous medium Another approach involves the synthesis of hydrophobic water-insoluble polymers in which the major fraction of the drug is released by erosion of the polymer matrix . . ."); p.588 ("Hydrophobic polymer solubilization can be achieved as a result of a chemical reaction that takes place at either a pendant group of the polymer or within the polymer backbone. When the reaction is confined to the pendant group, no backbone cleavage takes place, and one of the reaction products is a hydrolytically stable water-soluble polymer. . . . Hydrophobic polymers can also be solubilized by an ionization reaction of pendant carboxyl groups; drug dissolution and release rate kinetics are obtained from partially esterified copolymers derived from ethylene-maleic anhydride or methyl vinyl ester-maleic anhydride.").

Kim: p194-96; Fig.4; 197-201 ("Drug Diffusion through Polymers"); p.202-204 ("Release Rate from Monolithic Devices"); p.204-206 ("Mechanistic Considerations of Drug Diffusion through Polymer Membranes"); p.215-220 ("Hydrophobic Polymers as Drug Carriers") ("Ethylene-Vinyl Acetate Copolymer (EVA)"); p.220-23 ("The synthesis of biodegradable polymers for controlled drug release is based on different strategies. 1. A degradable polymer medium to which a drug is dispersed. Here drug diffusion through the polymer matrix is influenced by the degradation of the polymeric material. 2. A degradable polymer medium to which a drug is attached through a hydrolytically labile linkage. Drug release is controlled by both hydrolysis of the drug from the polymer and by diffusion of the drug through the polymer matrix."); p.226-28 ("Design of Chemically Bound Polymer-Bioactive Agent (PBA) Systems"); p.228-29 ("Models of Chemically Bound Polymer-Bioactive Agent Systems."); p.229-46 ("Examples of Chemically Bound Polymer-Bioactive Agent Systems").

Dev: Abstract; p. 273 ("The purpose of this study was twofold: first, to test a polymer-coated removable stent system for local delivery of two lipid soluble drugs . . . and second, to compare these two drugs with respect to kinetics of their delivery to the arterial wall with the stent in place and their tissue washout rates after removal of the stent."), ("We used a commercially available biomedical grade polyurethane [as a stent coating]. . . . To study the kinetics of drug delivery, we used two lipid soluble compounds: forskolin and etretinate."), ("Ratio of peak drug levels in the vessel wall to those in the blood was 6,000 for etretinate and 780 for forskolin. . . . Polymer-coated stents could be used for local drug delivery to the vessel wall."); p. 274-75 ("the drug levels [of etretinate] in blood and the distant tissues are extremely low, and the ratio of local to systemic drug levels is very high (~6,000); p. 277 ("This [preferential release of drug into the arterial wall] may reflect slower diffusion of etretinate in the aqueous medium than forskolin or presence of significant tissue binding of etretinate.").

Claim 4 [4A]: The device of claim 1 whereby the apposition of the device adjacent to the damaged tissue forms a chamber,

Where Found in the Prior References:

Schwartz '823: Abstract ("The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen."); Figs. 6-9, 13, 15; col. 2:37-40 ("In essence, this improvement makes it possible to provide a stent able to support body lumens and conform to curves or irregularities in body lumens."); col. 2:44-54 ("The composite stent of the present invention can be delivered to the site of the occlusion by catheter and expanded conventionally, causing the film to expand or open radially along with the metallic elements of the stent and to be brought into contact with the body lumen. The polymeric film is flexible and preferably an elastic or stretchable film that is capable of conforming to the movement of the metallic stent elements when expanded into contact with a body lumen."); col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:48-54; col. 3:58-col. 4:6; col. 6:49-52 ("As shown in Fig. 13, the stent can be delivered to the body lumen and expanded (e.g. by use of a balloon catheter) into contact with the body lumen."); col. 6:33-37 ("As shown in Fig. 9, with the angioplasty procedure completed, balloon is deflated and withdrawn leaving stent firmly implanted within vessel with the film held in contact with the vessel."); col. 6:62-68 ("Once in the desired location, the stent can be released from the catheter and expanded into contact with the lumen as shown in Fig. 15 where it can conform to the curvature of the body lumen. The flexible film is able to form folds which allow the stent elements to readily adapt to the curvature of the body lumen.").

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14 ("The present invention satisfies this need by providing a separate sleeve to encompass the stent and serve as a local drug delivery device to prevent thrombosis."); col. 4:53-55 ("The present invention satisfies this need by providing a separate sleeve to encompass a stent to locally administer drugs to prevent restenosis."); col. 4:58-68 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. . . . Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 5:26-29; col. 6:49-55 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of

promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface"); col. 8:8-22; col. 8:58-60 ("The films were placed to line the circumference of a 2 cm length of ePTFE grafts, over which a 2 cm long stent was deployed."); col. 9:12-16 ("In addition, polymer-drug films which prevent thrombosis in the baboon and pig AV shunt system can be studied following stent-film placement in carotid, superficial femoral and coronary arteries following balloon injury of those vessels."); col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Fig. 8; col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:12-20 ("Stents are typically implanted within a vessel in a contracted state and expanded when in place in the vessel in order to maintain patency of the vessel to allow fluid flow through the vessel. Ideally, the implantation of such stents is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:50-56 ("The stent can be used in coronary arteries or any other part of the vasculature or other body lumen where mechanical opening force is necessary or desirable to keep the vessel open or to maintain the stent flush against the lumen wall, and where an anti-restenosis, anti-proliferative or other types of therapeutic drug or agent is to be simultaneously positioned and diffused."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 2:23-33; col. 5:15-17; col. 7:56-62; col. 9:63-

67 ("The deployment of the stent can also be improved by . . . decreasing friction between the vessel or lumen wall and the stent."); col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:52-54 ("The invention provides prostheses which may be inserted into a lumen of a body and fixed to the lumen wall adjacent an area needing treatment."); col. 1:63-66 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery."); col. 2:7-9 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:25-27 ("The current invention contemplates the usage of any prosthesis which elutes drugs locally to treat a lumen in need of repair."); col. 6:36-38; col. 6:56-58 ("The stent shown in Figs. 2 and 4 is a metallic malleable design which may be forced against a lumen wall by a balloon catheter which fixes it into position."); col. 6:64-67 ("The variations of design shown in the embodiments of Figs. 1 and 2 show that the prosthesis of the invention must be secured against a lumen wall and must carry a drug-eluting polymer."); col. 9:67-10:3 ("By including a metal stent within the lumen of the polymeric prosthesis, the polymeric prosthesis is effectively held against the wall of the body lumen by the strength of the metal stent."); col. 10:23-38 ("The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen. This will bring the bioabsorbable element into supporting contact with a body lumen at an interior position of the body lumen to be treated and will position the bioabsorbable element to deliver drugs to the body lumen. Following the expansion of the stents into luminal contact, the balloon (if the expansion device is a balloon) can be deflated which allows the luminal flow to be restored."); col. 10:46-59; col. 11:10-13; col. 11:17-20; col. 11:50-53 ((b) a body including a plurality of support elements forming an open-ended, radially expandable, self-supporting tubular structuring having an interior surface and an exterior surface."); col. 12:1-15.

Berg '354: Page 2:14-18 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen. Examples of stents which have been successfully applied over a PTCA balloon and radially expanded at the same time as the balloon expansion of an affected artery include the stents disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) which are incorporated herein by reference in their entirety."); p. 2:34-36 ("Metal stents such as those disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) could be suitable for drug delivery in that they are capable of maintaining intimate contact between a substance applied to the outer surface of the stent and the tissues of the vessel to be treated."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting

polymeric surface on the stent."); p. 3:16-18 ("In operation, the stent made according to the present invention can deliver drugs to a body lumen by introducing the stent transluminally into a selected portion of the body lumen and radially expanding the stent into contact with the body lumen.").

Buscemi '450: Col. 3:14-15 ("The stent strengthens an area of the vessel that is in contact with the stent."); col. 3:21-25 ("The tubular main body includes an outer surface and inner surface. The outer surface of the main body faces an inner surface wall of the vessel. The inner surface of the stent faces a stream flowing through the lumen as shown in cross section in Fig. 2."); col. 4:61-64 ("The stent is secured by releasing the stent from compression so that the stent can radially spring out to abut against the inner surface wall of the vessel."); col. 6:49-52; col. 7:27-29; col. 8:9-11.

Ding '536: Col. 5:38-40 ("Surface material should minimize tissue rejection and tissue inflammation and permit encapsulation by tissue adjacent the stent implantation site.").

Dinh '227: Col. 1:32-35 ("The stent is typically inserted by catheter into a vascular lumen told [sic] expanded into contact with the diseased portion of the arterial wall, thereby providing mechanical support for the lumen."); col. 8:20-23 ("The term "stent" herein means any device which when placed into contact with a site in the wall of a lumen to be treated, will also place fibrin at the lumen wall and retain it at the lumen wall."); col. 8:37-43; col. 9:18-24 ("The stent is then delivered through the body lumen on the catheter to the treatment site where the stent is released from the catheter to allow it to expand into contact with the lumen wall.").

Domb '055: Abstract ("Preferred embodiments include catheters, tubes, and implants that abut tissue following implantation into the body . . ."); col. 4:25-32; col. 5:27-33; col. 5:49-54; col. 5:63-6:1 ("Coating that part of the tube, which is in contact with the mucosa, with the drug-loaded polymer provides a sustained release of steroids and antibiotics locally and at high concentration in the area which is critically affected, achieving the same effect as the systemic administration of the drugs without their side effects, throughout the duration of the intubation."); col. 6:8-18; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages.").

Kowligi '782: Abstract; col. 1:18-41; Figs. 2, 3; col. 10:18-67.

Hunter '981: Col. 4:24-38; col. 5:1-6; col. 16:31-56; col. 22:3-7; col. 22:54-58; col. 23:6-13 ("[M]ethods are provided for expanding the lumen of a body passageway, comprising inserting a stent into the passageway, the stent having a generally tubular structure, the surface of the structure being coated with an anti-angiogenic composition . . . such that the passageway is expanded."); col. 23:30-31; col. 23:46-51; col. 24:45-51; col. 24:66-25:5; col. 25:24-29; col. 25:48-54; col. 52:4-8 ("This film is designed to be placed on exposed tissue so that any encapsulated drug is released from the polymer over a long period of time at the tissue site."); 86:56-59; col. 87:11-22; col. 88:19-26.

Lambert '922: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion."); col. 3:54-61; col. 8:1-6.

Lambert '308: Page 3:24-27 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion.").

Myler '563: Col. 3:34-37 ("Stent 10 is illustrated in its expanded position at a treatment location adjacent vascular wall in an artery, in accordance with one aspect of the present invention."); col. 4:53-56 ("The exterior surface of the envelope which will contact the arterial wall is optionally made porous to enable the release of drugs from the envelope and/or stent to the treatment site."); col. 10:12-14 ("The balloon is inflated, thereby expanding the stent radially outwardly until it contacts either a previously dilated, or presently stenosed wall."); col. 10:56-61; col. 11:63-65 ("Once the stent has been positioned at the treatment site, axial elongating tension is released, and it is permitted to radially expand against the lumen wall."); col. 13:15-17 ("The exterior coating which will contact the arterial wall is optionally made porous to enable the release of drugs to the treatment site.").

Palmaz '417: col. 4:25-37 (" . . . expanding a portion of the catheter associated with the prostheses to force at least one of the prostheses radially outward into contact with the body passageway . . .").

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); Figs. 1 and 2; col. 9:18-10:3.

Strecker '746: Figs. 7 & 8.

Schiraldi '243: Col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-

soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Valentini '029: Col. 2:39-41 ("The tubular membrane defines a lumen through which axons can be regenerated to restore motor and/or sensory functions."); Figure 3; col. 2:32-35 ("Medical devices employing such selectively permeable materials, particularly semipermeable tubular devices having smooth inner skins, are disclosed for use in regenerating nerves.").

Bawa '279: Col. 6:40-44; col. 12:29-34.

Wood '066: Col. 2:67-3:32 ("The object of this invention is to provide means for delivery effective dosages of therapeutic agents to sites of trauma such as wounds, thermal or chemical burns, ulcers, lesions, or surgical sites.").

Aebischer '486: Fig. 1.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:63-2:2; col. 2:21-32; col. 2:33-38; col. 2:39-46; col. 3:63-4:31 ("It can be of advantage for the lining to be of several layers, each impregnated with different medications. . . . It has also been demonstrated practical for the inner layer of the lining to be impregnated with antithrombotics and the outer with antiproliferatives and/or other medicational substances."); Fig. 4; col. 5:18-20 ("Fig. 4 is a view similar to that of Fig. 2 of an endoprosthesis with a multiple-layer lining and with its ends coated with medication,"); col. 5:34-41 ("The endoprosthesis . . . is completely enclosed in an inner lining component and an outer lining component."); Fig. 7; col. 6:30-44 ("The endoprosthesis 40 in the embodiment illustrated in Fig. 7 comprises a lining 42 and 43 in the form of a double walled sleeve. The outer lining component 43 of the in-place and expanded stent rests against the inner surface 46 of the blood vessel. Inner lining component 42 rests against the stent."); col. 7:16-35; col. 7:48-65; col. 8:19-10:19.

Lambert '246: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion.").

Bellamkonda '029: Fig. 6.

Dayton '382: Abstract ("The stent is then coated with a polymer or is formed from a polymer which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids . . ."); col. 4:4-10; col. 6:64-7:7; col. 8:18-19 ("a polymer forming the exterior surface of said stent for operative contact with said tissue . . .").

Burt '036: p.14:9-27; p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of

insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size.").

Goldin '568: Figs. 5A-5F; col. 9:7-12 ("... a substance that, when implanted in or juxtaposed against a living body . . ."); col. 22:46-23:3.

Palmaz '665: Col 8:59-64 ("Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80."); col. 5: 25-29; Figure 4.

Palmaz '762: col. 4: 14-19 (...expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway..."); col. 4: 53-56; col. 5: 43-45; col. 9: 1-6; col 9:68-10:10 ("Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80."); Figure 4.

Palmaz '337: Col. 3:60-4:2 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into a body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded, whereby the intraluminal graft prevents the body passageway from collapsing and decreasing the size of the expanded lumen."); col. 4: 36-40; col. 5: 32-34; col. 7: 28-36; col. 8: 17-22; col. 8:67-9:8 ("Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80."); Figure 4.

Claim 4 [4B] (cont'd): one wall of the chamber
being formed by the layer,

Where Found in the Prior References:

Schwartz '823: Abstract ("The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen."); Figs. 6-9, 13, 15; col. 2:37-40 ("In essence, this improvement makes it possible to provide a stent able to support body lumens and conform to curves or irregularities in body lumens."); col. 2:44-54 ("The composite stent of the present invention can be delivered to the site of the occlusion by catheter and expanded conventionally, causing the film to expand or open radially along with the metallic elements of the stent and to

be brought into contact with the body lumen. The polymeric film is flexible and preferably an elastic or stretchable film that is capable of conforming to the movement of the metallic stent elements when expanded into contact with a body lumen."); col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:48-54; col. 3:58-col. 4:6; col. 6:49-52 ("As shown in Fig. 13, the stent can be delivered to the body lumen and expanded (e.g. by use of a balloon catheter) into contact with the body lumen."); col. 6:33-37 ("As shown in Fig. 9, with the angioplasty procedure completed, balloon is deflated and withdrawn leaving stent firmly implanted within vessel with the film held in contact with the vessel."); col. 6:62-68 ("Once in the desired location, the stent can be released from the catheter and expanded into contact with the lumen as shown in Fig. 15 where it can conform to the curvature of the body lumen. The flexible film is able to form folds which allow the stent elements to readily adapt to the curvature of the body lumen.").

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14 ("The present invention satisfies this need by providing a separate sleeve to encompass the stent and serve as a local drug delivery device to prevent thrombosis."); col. 4:53-55 ("The present invention satisfies this need by providing a separate sleeve to encompass a stent to locally administer drugs to prevent restenosis."); col. 4:58-68 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. . . . Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 5:26-29; col. 6:49-55 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface); col. 8:8-22; col. 8:58-60 ("The films were placed to line the circumference of a 2 cm length of ePTFE grafts, over which a 2 cm long stent was deployed."); col. 9:12-16 ("In addition, polymer-drug films which prevent thrombosis in the baboon and pig AV shunt system can be studied following stent-film placement in carotid, superficial femoral and coronary arteries following balloon injury of those vessels."); col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be

released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Fig. 8; col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:12-20 ("Stents are typically implanted within a vessel in a contracted state and expanded when in place in the vessel in order to maintain patency of the vessel to allow fluid flow through the vessel. Ideally, the implantation of such stents is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:50-56 ("The stent can be used in coronary arteries or any other part of the vasculature or other body lumen where mechanical opening force is necessary or desirable to keep the vessel open or to maintain the stent flush against the lumen wall, and where an anti-restenosis, anti-proliferative or other types of therapeutic drug or agent is to be simultaneously positioned and diffused."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 2:23-33; col. 5:15-17; col. 7:56-62; col. 9:63-67 ("The deployment of the stent can also be improved by . . . decreasing friction between the vessel or lumen wall and the stent."); col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:52-54 ("The invention provides prostheses which may be inserted into a lumen of a body and fixed to the lumen wall adjacent an area needing treatment."); col. 1:63-66 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery."); col. 2:7-9 ("The prosthesis

comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:25-27 ("The current invention contemplates the usage of any prosthesis which elutes drugs locally to treat a lumen in need of repair."); col. 6:36-38; col. 6:56-58 ("The stent shown in Figs. 2 and 4 is a metallic malleable design which may be forced against a lumen wall by a balloon catheter which fixes it into position."); col. 6:64-67 ("The variations of design shown in the embodiments of Figs. 1 and 2 show that the prosthesis of the invention must be secured against a lumen wall and must carry a drug-eluting polymer."); col. 9:67-10:3 ("By including a metal stent within the lumen of the polymeric prosthesis, the polymeric prosthesis is effectively held against the wall of the body lumen by the strength of the metal stent."); col. 10:23-38 ("The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen. This will bring the bioabsorbable element into supporting contact with a body lumen at an interior position of the body lumen to be treated and will position the bioabsorbable element to deliver drugs to the body lumen. Following the expansion of the stents into luminal contact, the balloon (if the expansion device is a balloon) can be deflated which allows the luminal flow to be restored."); col. 10:46-59; col. 11:10-13; col. 11:17-20; col. 11:50-53 ((b) a body including a plurality of support elements forming an open-ended, radially expandable, self-supporting tubular structuring having an interior surface and an exterior surface."); col. 12:1-15.

Berg '354: Page 2:14-18 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen. Examples of stents which have been successfully applied over a PTCA balloon and radially expanded at the same time as the balloon expansion of an affected artery include the stents disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) which are incorporated herein by reference in their entirety."); p. 2:34-36 ("Metal stents such as those disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) could be suitable for drug delivery in that they are capable of maintaining intimate contact between a substance applied to the outer surface of the stent and the tissues of the vessel to be treated."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:16-18 ("In operation, the stent made according to the present invention can deliver drugs to a body lumen by introducing the stent transluminally into a selected portion of the body lumen and radially expanding the stent into contact with the body lumen.").

Buscemi '450: Col. 3:14-15 ("The stent strengthens an area of the vessel that is in contact with the stent."); col. 3:21-25 ("The tubular main body includes an outer surface and inner surface. The outer surface of the main body faces an inner surface wall of the vessel. The inner surface of the stent faces a stream flowing through the lumen as shown in cross section in Fig. 2."); col. 4:61-64 ("The stent is secured by releasing the stent from compression so that the stent

can radially spring out to abut against the inner surface wall of the vessel."); col. 6:49-52; col. 7:27-29; col. 8:9-11.

Ding '536: Col. 5:38-40 ("Surface material should minimize tissue rejection and tissue inflammation and permit encapsulation by tissue adjacent the stent implantation site.").

Dinh '227: Col. 1:32-35 ("The stent is typically inserted by catheter into a vascular lumen told [sic] expanded into contact with the diseased portion of the arterial wall, thereby providing mechanical support for the lumen."); col. 8:20-23 ("The term "stent" herein means any device which when placed into contact with a site in the wall of a lumen to be treated, will also place fibrin at the lumen wall and retain it at the lumen wall."); col. 8:37-43; col. 9:18-24 ("The stent is then delivered through the body lumen on the catheter to the treatment site where the stent is released from the catheter to allow it to expand into contact with the lumen wall.").

Domb '055: Abstract ("Preferred embodiments include catheters, tubes, and implants that abut tissue following implantation into the body . . ."); col. 4:25-32; col. 5:27-33; col. 5:49-54; col. 5:63-6:1 ("Coating that part of the tube, which is in contact with the mucosa, with the drug-loaded polymer provides a sustained release of steroids and antibiotics locally and at high concentration in the area which is critically affected, achieving the same effect as the systemic administration of the drugs without their side effects, throughout the duration of the intubation."); col. 6:8-18; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages.").

Kowligi '782: Abstract; col. 1:18-41; Figs. 2, 3; col. 10:18-67.

Hunter '981: Col. 4:24-38; col. 5:1-6; col. 16:31-56; col. 22:3-7; col. 22:54-58; col. 23:6-13 ("[M]ethods are provided for expanding the lumen of a body passageway, comprising inserting a stent into the passageway, the stent having a generally tubular structure, the surface of the structure being coated with an anti-angiogenic composition . . . such that the passageway is expanded."); col. 23:30-31; col. 23:46-51; col. 24:45-51; col. 24:66-25:5; col. 25:24-29; col. 25:48-54; col. 52:4-8 ("This film is designed to be placed on exposed tissue so that any encapsulated drug is released from the polymer over a long period of time at the tissue site."); 86:56-59; col. 87:11-22; col. 88:19-26.

Lambert '922: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion."); col. 3:54-61; col. 8:1-6.

Lambert '308: Page 3:24-27 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion.").

Myler '563: Col. 3:34-37 ("Stent 10 is illustrated in its expanded position at a treatment location adjacent vascular wall in an artery, in accordance with one aspect of the present invention."); col. 4:53-56 ("The exterior surface of the envelope which will contact the arterial wall is optionally made porous to enable the release of drugs from the envelope and/or stent to the treatment site."); col. 10:12-14 ("The balloon is inflated, thereby expanding the stent radially outwardly until it contacts either a previously dilated, or presently stenosed wall."); col. 10:56-61; col. 11:63-65 ("Once the stent has been positioned at the treatment site, axial elongating tension is released, and it is permitted to radially expand against the lumen wall."); col. 13:15-17 ("The exterior coating which will contact the arterial wall is optionally made porous to enable the release of drugs to the treatment site.").

Palmaz '417: col. 4:25-37 (" . . . expanding a portion of the catheter associated with the prostheses to force at least one of the prostheses radially outward into contact with the body passageway . . .").

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); Figs. 1 and 2; col. 9:18-10:3.

Strecker '746: Figs. 7 & 8.

Schiraldi '243: Col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Valentini '029: Col. 2:39-41 ("The tubular membrane defines a lumen through which axons can be regenerated to restore motor and/or sensory functions."); Figure 3; col. 2:32-35 ("Medical devices employing such selectively permeable materials, particularly semipermeable tubular devices having smooth inner skins, are disclosed for use in regenerating nerves.").

Bawa '279: Col. 6:40-44; col. 12:29-34.

Wood '066: Col. 2:67-3:32 ("The object of this invention is to provide means for delivery effective dosages of therapeutic agents to sites of trauma such as wounds, thermal or chemical burns, ulcers, lesions, or surgical sites.").

Aebischer '486: Fig. 1.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:63-2:2; col. 2:21-32; col. 2:33-38; col. 2:39-46; col. 3:63-4:31 ("It can be of advantage for the lining to be of several layers, each impregnated with different medications. . . . It has also been demonstrated practical for the inner layer of the lining to be impregnated with antithrombotics and the outer with antiproliferatives and/or other medicational substances."); Fig. 4; col. 5:18-20 ("Fig. 4 is a view similar to that of Fig. 2 of an endoprosthesis with a multiple-layer lining and with its ends coated with medication,"); col. 5:34-41 ("The endoprosthesis . . . is completely enclosed in an inner lining component and an outer lining component."); Fig. 7; col. 6:30-44 ("The endoprosthesis 40 in the embodiment illustrated in Fig. 7 comprises a lining 42 and 43 in the form of a double walled sleeve. The outer lining component 43 of the in-place and expanded stent rests against the inner surface 46 of the blood vessel. Inner lining component 42 rests against the stent."); col. 7:16-35; col. 7:48-65; col. 8:19-10:19.

Lambert '246: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion.").

Bellamkonda '029: Fig. 6.

Dayton '382: Abstract ("The stent is then coated with a polymer or is formed from a polymer which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids . . ."); col. 4:4-10; col. 6:64-7:7; col. 8:18-19 ("a polymer forming the exterior surface of said stent for operative contact with said tissue . . .").

Burt '036: p.14:9-27; p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size.").

Goldin '568: Figs. 5A-5F; col. 9:7-12 (" . . . a substance that, when implanted in or juxtaposed against a living body . . ."); col. 22:46-23:3.

Palmaz '665: Col 8:59-64 ("Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80."); col. 5: 25-29; Figure 4.

Palmaz '762: col. 4: 14-19 (...expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway..."); col. 4: 53-56; col. 5: 43-45; col. 9: 1-6; col 9:68-10:10 ("Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80."); Figure 4.

Palmaz '337: Col. 3:60-4:2 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into a body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded, whereby the intraluminal graft prevents the body passageway from collapsing and decreasing the size of the expanded lumen."); col. 4: 36-40; col. 5: 32-34; col. 7: 28-36; col. 8: 17-22; col. 8:67-9:8 ("Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80."); Figure 4.

Claim 4 [4C] (cont'd): one wall of the chamber
being formed by the damage tissue,

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catheter) into contact with the body lumen."); col. 6:33-37 ("As shown in Fig. 9, with the angioplasty procedure completed, balloon is deflated and withdrawn leaving stent firmly implanted within vessel with the film held in contact with the vessel."); col. 6:62-68 ("Once in the desired location, the stent can be released from the catheter and expanded into contact with the lumen as shown in Fig. 15 where it can conform to the curvature of the body lumen. The flexible film is able to form folds which allow the stent elements to readily adapt to the curvature of the body lumen.").

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14 ("The present invention satisfies this need by providing a separate sleeve to encompass the stent and serve as a local drug delivery device to prevent thrombosis."); col. 4:53-55 ("The present invention satisfies this need by providing a separate sleeve to encompass a stent to locally administer drugs to prevent restenosis."); col. 4:58-68 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. . . . Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 5:26-29; col. 6:49-55 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface); col. 8:8-22; col. 8:58-60 ("The films were placed to line the circumference of a 2 cm length of ePTFE grafts, over which a 2 cm long stent was deployed."); col. 9:12-16 ("In addition, polymer-drug films which prevent thrombosis in the baboon and pig AV shunt system can be studied following stent-film placement in carotid, superficial femoral and coronary arteries following balloon injury of those vessels."); col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Fig. 8; col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:12-20 ("Stents are typically implanted within a vessel in a contracted state and expanded when in place in the vessel in order to maintain patency of the vessel to allow fluid flow through the vessel. Ideally, the implantation of such stents is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:50-56 ("The stent can be used in coronary arteries or any other part of the vasculature or other body lumen where mechanical opening force is necessary or desirable to keep the vessel open or to maintain the stent flush against the lumen wall, and where an anti-restenosis, anti-proliferative or other types of therapeutic drug or agent is to be simultaneously positioned and diffused."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 2:23-33; col. 5:15-17; col. 7:56-62; col. 9:63-67 ("The deployment of the stent can also be improved by . . . decreasing friction between the vessel or lumen wall and the stent."); col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:52-54 ("The invention provides prostheses which may be inserted into a lumen of a body and fixed to the lumen wall adjacent an area needing treatment."); col. 1:63-66 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery."); col. 2:7-9 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:25-27 ("The current invention contemplates the usage of any prosthesis which elutes drugs locally to treat a lumen in need of repair."); col. 6:36-38; col. 6:56-58 ("The stent shown in Figs. 2 and 4 is a metallic malleable design which may be forced against a lumen wall by a balloon catheter which fixes it into position."); col. 6:64-67 ("The variations of design shown in the embodiments of Figs. 1 and 2 show that the prosthesis of the invention must be secured against a lumen wall and must carry a drug-eluting polymer."); col. 9:67-10:3 ("By including a metal stent within the lumen of the polymeric prosthesis, the polymeric prosthesis is effectively held against the wall of the body lumen by the strength of the metal stent."); col.

10:23-38 ("The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen. This will bring the bioabsorbable element into supporting contact with a body lumen at an interior position of the body lumen to be treated and will position the bioabsorbable element to deliver drugs to the body lumen. Following the expansion of the stents into luminal contact, the balloon (if the expansion device is a balloon) can be deflated which allows the luminal flow to be restored."); col. 10:46-59; col. 11:10-13; col. 11:17-20; col. 11:50-53 ((b) a body including a plurality of support elements forming an open-ended, radially expandable, self-supporting tubular structuring having an interior surface and an exterior surface."); col. 12:1-15.

Berg '354: Page 2:14-18 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen. Examples of stents which have been successfully applied over a PTCA balloon and radially expanded at the same time as the balloon expansion of an affected artery include the stents disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) which are incorporated herein by reference in their entirety."); p. 2:34-36 ("Metal stents such as those disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) could be suitable for drug delivery in that they are capable of maintaining intimate contact between a substance applied to the outer surface of the stent and the tissues of the vessel to be treated."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:16-18 ("In operation, the stent made according to the present invention can deliver drugs to a body lumen by introducing the stent transluminally into a selected portion of the body lumen and radially expanding the stent into contact with the body lumen.").

Buscemi '450: Col. 3:14-15 ("The stent strengthens an area of the vessel that is in contact with the stent."); col. 3:21-25 ("The tubular main body includes an outer surface and inner surface. The outer surface of the main body faces an inner surface wall of the vessel. The inner surface of the stent faces a stream flowing through the lumen as shown in cross section in Fig. 2."); col. 4:61-64 ("The stent is secured by releasing the stent from compression so that the stent can radially spring out to abut against the inner surface wall of the vessel."); col. 6:49-52; col. 7:27-29; col. 8:9-11.

Ding '536: Col. 5:38-40 ("Surface material should minimize tissue rejection and tissue inflammation and permit encapsulation by tissue adjacent the stent implantation site.").

Dinh '227: Col. 1:32-35 ("The stent is typically inserted by catheter into a vascular lumen told [sic] expanded into contact with the diseased portion of the arterial wall, thereby providing mechanical support for the lumen."); col. 8:20-23 ("The term "stent" herein means any device which when placed into contact with a site in the wall of a lumen to be treated, will also place

fibrin at the lumen wall and retain it at the lumen wall."); col. 8:37-43; col. 9:18-24 ("The stent is then delivered through the body lumen on the catheter to the treatment site where the stent is released from the catheter to allow it to expand into contact with the lumen wall.").

Domb '055: Abstract ("Preferred embodiments include catheters, tubes, and implants that abut tissue following implantation into the body . . ."); col. 4:25-32; col. 5:27-33; col. 5:49-54; col. 5:63-6:1 ("Coating that part of the tube, which is in contact with the mucosa, with the drug-loaded polymer provides a sustained release of steroids and antibiotics locally and at high concentration in the area which is critically affected, achieving the same effect as the systemic administration of the drugs without their side effects, throughout the duration of the intubation."); col. 6:8-18; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages.").

Kowligi '782: Abstract; col. 1:18-41; Figs. 2, 3; col. 10:18-67.

Hunter '981: Col. 4:24-38; col. 5:1-6; col. 16:31-56; col. 22:3-7; col. 22:54-58; col. 23:6-13 ("[M]ethods are provided for expanding the lumen of a body passageway, comprising inserting a stent into the passageway, the stent having a generally tubular structure, the surface of the structure being coated with an anti-angiogenic composition . . . such that the passageway is expanded."); col. 23:30-31; col. 23:46-51; col. 24:45-51; col. 24:66-25:5; col. 25:24-29; col. 25:48-54; col. 52:4-8 ("This film is designed to be placed on exposed tissue so that any encapsulated drug is released from the polymer over a long period of time at the tissue site."); 86:56-59; col. 87:11-22; col. 88:19-26.

Lambert '922: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion."); col. 3:54-61; col. 8:1-6.

Lambert '308: Page 3:24-27 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion.").

Myler '563: Col. 3:34-37 ("Stent 10 is illustrated in its expanded position at a treatment location adjacent vascular wall in an artery, in accordance with one aspect of the present invention."); col. 4:53-56 ("The exterior surface of the envelope which will contact the arterial wall is optionally made porous to enable the release of drugs from the envelope and/or stent to

the treatment site."); col. 10:12-14 ("The balloon is inflated, thereby expanding the stent radially outwardly until it contacts either a previously dilated, or presently stenosed wall."); col. 10:56-61; col. 11:63-65 ("Once the stent has been positioned at the treatment site, axial elongating tension is released, and it is permitted to radially expand against the lumen wall."); col. 13:15-17 ("The exterior coating which will contact the arterial wall is optionally made porous to enable the release of drugs to the treatment site.").

Palmaz '417: col. 4:25-37 (" . . . expanding a portion of the catheter associated with the prostheses to force at least one of the prostheses radially outward into contact with the body passageway . . .").

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); Figs. 1 and 2; col. 9:18-10:3.

Strecker '746: Figs. 7 & 8.

Schiraldi '243: Col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Valentini '029: Col. 2:39-41 ("The tubular membrane defines a lumen through which axons can be regenerated to restore motor and/or sensory functions."); Figure 3; col. 2:32-35 ("Medical devices employing such selectively permeable materials, particularly semipermeable tubular devices having smooth inner skins, are disclosed for use in regenerating nerves.").

Bawa '279: Col. 6:40-44; col. 12:29-34.

Wood '066: Col. 2:67-3:32 ("The object of this invention is to provide means for delivery effective dosages of therapeutic agents to sites of trauma such as wounds, thermal or chemical burns, ulcers, lesions, or surgical sites.").

Aebischer '486: Fig. 1.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide

lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:63-2:2; col. 2:21-32; col. 2:33-38; col. 2:39-46; col. 3:63-4:31 ("It can be of advantage for the lining to be of several layers, each impregnated with different medications. . . . It has also been demonstrated practical for the inner layer of the lining to be impregnated with antithrombotics and the outer with antiproliferatives and/or other medicational substances."); Fig. 4; col. 5:18-20 ("Fig. 4 is a view similar to that of Fig. 2 of an endoprosthesis with a multiple-layer lining and with its ends coated with medication,"); col. 5:34-41 ("The endoprosthesis . . . is completely enclosed in an inner lining component and an outer lining component."); Fig. 7; col. 6:30-44 ("The endoprosthesis 40 in the embodiment illustrated in Fig. 7 comprises a lining 42 and 43 in the form of a double walled sleeve. The outer lining component 43 of the in-place and expanded stent rests against the inner surface 46 of the blood vessel. Inner lining component 42 rests against the stent."); col. 7:16-35; col. 7:48-65; col. 8:19-10:19.

Lambert '246: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion.").

Bellamkonda '029: Fig. 6.

Dayton '382: Abstract ("The stent is then coated with a polymer or is formed from a polymer which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids . . ."); col. 4:4-10; col. 6:64-7:7; col. 8:18-19 ("a polymer forming the exterior surface of said stent for operative contact with said tissue . . .").

Burt '036: p.14:9-27; p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size.").

Goldin '568: Figs. 5A-5F; col. 9:7-12 (" . . . a substance that, when implanted in or juxtaposed against a living body . . ."); col. 22:46-23:3.

Palmaz '665: Col 8:59-64 ("Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80."); col. 5: 25-29; Figure 4.

Palmaz '762: col. 4: 14-19 (...expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway..."); col. 4: 53-56; col. 5: 43-45; col. 9: 1-6; col 9:68-10:10 ("Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80."); Figure 4.

Palmaz '337: Col. 3:60-4:2 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into a body passageway until it is

disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded, whereby the intraluminal graft prevents the body passageway from collapsing and decreasing the size of the expanded lumen."); col. 4: 36-40; col. 5: 32-34; col. 7: 28-36; col. 8: 17-22; col. 8:67-9:8 ("Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80."); Figure 4.

Claim 4 [4D] (cont'd): such that the formed chamber contains a greater concentration of at least one type of macromolecule compared to outside the chamber.

Where Found in the Prior References:

Schwartz '823: Abstract; col. 2:29-40; col. 2:49-53; col. 3:58-61 ("The improvement of the present invention includes applying to the above-mentioned type of stent a flexible or elastomeric polymeric film which extends between the metal elements."); col. 3:64-4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof."); col. 6:17-20; col. 7:25-8:11.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); Fig. 3; col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-33; col. 5:34-6:29; col. 6:37-41; col. 6:41-45 ("Modifications of the polymer coating include a ring that encompasses the proximal portion of the stent, single or multiple strips that cover a portion of the stent, or a polymer coating with perforations."); col. 8:23-25 ("Ethylene vinyl acetate copolymer (EVA) (Catalog #34,691-8) was obtained from Aldrich Chemical Company, Inc. (Milwaukee, Wis.); col. 10:24-33; col. 12:1-6; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial

lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow Controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Col. 1:7-10 ("This invention relates generally to expandable intraliminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 1:64-2:2 ("The polymer material can be a thermoplastic or an elastomer, for example, so that the film can stretch or deform radially when the stent structural member is expanded. The film of polymer material can be formed as a solid sheet, or can incorporate holes of various sizes and shapes to promote rapid endothelialization."); col. 4:15-24; col. 4:25-46; col. 4:47-5:3; col. 5:4-9; col. 5:49- 6:25 ("The polymeric material is preferably selected from thermoplastic and elastomeric polymers. . . . In another currently preferred embodiment, the polymeric material can be ethylene vinyl acetate (EVA) . . ."); col. 6:26-65; col. 7:23-42; col. 7:63-65; col. 8:12-57; col. 9:5-12; col. 10:12-30.

Wolff '208: Col. 2:7-16 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:28-30 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 6:59-62 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously. The polymer may be biostable or bioabsorbable. If biostable, the drug would diffuse out of the polymer."); col. 6:64-67; col. 7:59-61; col. 9:23-33 ("That layer may be a simple barrier which limits diffusion of drugs in the polymer. In that event, the smaller molecules could elute out immediately, while larger compounds would not elute until later when the layer has biodegraded."); col. 12:37-40 ("8. The device of claim 1 also comprising a barrier coating of polymeric material on the drug-containing filament to limit the rate of drug elution.").

Berg '354: Page 2:43-54 ("Viewed from a further aspect the invention provides the use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug-eluting surface coating."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution

which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:29-31 ("Also, stents made with biostable or bioabsorbable polymers such as poly(ethylene terephthalate), polyacetal, poly(lactic acid), poly(ethylene oxide)/poly(butylene terephthalate) copolymer could be used in the present invention. "); Table 1; p. 4:5-24; p. 6:6-11; p. 6:15; p. 6:24-35; p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Abstract ("A stent made of biodegradable material includes a drug that is released at a rate controlled by the rate of degradation of the biodegradable material."); col. 2:16-17; col. 4:1-5 ("In one embodiment, the main body includes a film that is preferable combined with the plurality of fibers disposed around the main body. The film combined with the plurality of fibers defines the outer surface of the main body."); col. 4:15-16 ("Preferable, the main body of the stent includes a film covering the inner surface."); col. 4:19-22.

Ding '536: Abstract ("The coating includes a relatively thin layer of biostable elastomeric material containing an amount of biologically active material, particularly heparin, dispersed in the coating in combination with a non-thrombogenic surface."); col. 1:24-29 ("The present invention relates generally to providing biostable elastomeric coatings on the surfaces of implants which incorporate biologically active species having controlled release characteristics in the coating particularly to providing a non-thrombogenic surface during and after timed release of the biologically active species."); col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 5:10-56 ("Polymers generally suitable for the undercoats or underlayers include silicones (e.g., polysiloxanes and substituted polysiloxanes), polyurethanes, thermoplastic elastomers in general, ethylene vinyl acetate copolymers, polyolefin elastomers, polyamide elastomers, and EPDM rubbers. The above-referenced materials are considered hydrophobic with respect to the contemplated environment of the invention."); col. 12:62-13:2; col. 13:13-26; col. 13:37-40; col. 14:5-17; col. 14:22-34.

Dinh '227: Col. 2:51-54 ("To accomplish this while not affecting the strength of the overall fibrin stent structure, a first layer is applied to a stent body, the first layer incorporating a polymer and the therapeutic substance."); col. 2:62-66 ("The inclusion of a polymer in intimate contact with a drug on the underlying stent structure allows the drug to be retained on the stent in a resilient matrix during expansion of the stent and also slows the administration of drug following implantation."); col. 3:10-14; col. 3:25-38; col. 5:3-7; col. 5:44-55; col. 5:56-57; col. 6:13-19 ("In U.S. Pat. No. 4,548,736 issued to Muller et al., a dense fibrin composition is disclosed which can be a bioabsorbable matrix for delivery of drugs to a patient. Such a fibrin composition can also be used in the present invention by incorporating a drug or other therapeutic substance useful in diagnosis or treatment of body lumens to the fibrin provided on the stent."); 6:50-56 ("Alternatively . . . a dense fibrin composition suitable for drug delivery can be made without the use of microcapsules by adding the drug directly to the fibrin followed by

compression of the fibrin into a sufficiently dense matrix that a desired elution rate for the drug is achieved."); col. 6:62-67; col. 7:10-13; col. 7:56-64 ("In another embodiment of the invention, the coating of polymer and drug on the stent is achieved by forming a first fibrin layer on the stent body which incorporates the therapeutic substance and then applying a second layer of fibrin."); col. 8:52-60 ("Fig. 2 shows an alternative stent in which a fibrin film has been affixed to the underlying metallic framework by affixing it to the stent . . ."); col. 8:64-9:3; col. 12:24-28; col. 12:38-50.

Domb '055: Abstract ("Devices are provided having a polymer coating incorporating compounds inhibiting inflammation and infection, along with subsequent tissue growth onto and around the device. . . . Preferred polymeric coating are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); col. 1:12-15 ("This invention relates to invasive medical devices for delayed/sustained release of pharmaceutical compositions from a polymer that is coated or incorporated into the devices."); col. 3:54-57 ("In the preferred embodiments, these have utilized bioerodible polymers as the matrix for the drug to be released, usually as a function of diffusion and erosion of the polymer."); col. 4:22-36; col. 5:24-37; col. 5:41-45; col. 5:48-6:1; col. 6:24-26 ("Examples of suitable polymers include ethylene vinyl acetate, polyurethane, silicones, hydrogels, polyurethane, and polyvinyl chloride."); col. 7:10-20; col. 7:40-52; col. 9:15-30; col. 9:55-10:2; col. 10:21-52; col. 10:60-11:11; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 11:36-38 ("The medical device of claim 1, wherein the polymer is selected from the group consisting of polyurethane, ethylene vinyl acetate, silicones, hydrogels, and polyvinyl chloride."); col. 11:39-44; col. 12:11-22; col. 12:23-25; col. 12:26-31; col. 12:32-42.

Fox '096: Abstract ("A method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers, and antimicrobial agents . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 2:48-65; col. 3:55-67 ("The polymeric coating agent component of the coating vehicle of the present invention is selected from the group consisting of biomedical polyurethanes, biomedical silicones, biodegradable polymers and combinations thereof."); col. 19:11-16; col. 31:62-64.

Hunter '981: Col. 1:12-17; col. 3:42-45 ("Within one aspect of the present invention, compositions are provided (anti-angiogenic compositions) comprising (a) an anti-angiogenic

factor and (b) a polymeric carrier."); col. 3:53-61; col. 12:23-25 ("As noted above, the present invention provides compositions comprising an anti-angiogenic factor, and a polymeric carrier."); col. 16:31-56; col. 17:63-18:7 ("[T]he anti-angiogenic compositions of the present invention may be formed as a film. . . . Such films are preferably flexible with a good tensile strength . . . and has controlled permeability."); col. 22:3-7; col. 22:54-58; col. 47:58-49:7; col. 52:4-8; col. 69:19-62; col. 84:62-86:24; 86:56-59; col. 87:11-22; col. 88:19-26.

Kowligi '782: Abstract ("The elastomeric coating is made of polyurethane or another biocompatible non-porous elastomers and precludes tissue ingrowth into the outer cylindrical wall, minimizes suture hold bleeding, and increases suture retention strength, while reducing the incidence of serous weepage."); col. 1:18-26; col. 2:15-20; col. 2:38-47; col. 2:53-59; col. 3:27-37; Fig. 1; Fig. 2; Fig. 3; col. 2:60-67 ("PTFE tube 32 includes an inner cylindrical wall and an opposing outer cylindrical wall. As shown in Fig. 2, outer cylindrical wall 36 is coated entirely around its circumference by a uniformly thick coating of a biocompatible elastomer."); col. 3:27-38; col. 4:16-27 ("In regard to elastomeric coating 38 shown in Fig. 2, such elastomeric coating is selected to be a biocompatible elastomers and may be selected from the group consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 4:37-39 ("The elastomeric coating should also be sufficiently non-porous to preclude serous weepage and inhibit tissue ingrowth therethrough."); col. 5:4-7; col. 7:49-8:9; col. 8:38-44; col. 9:65-10:6; col. 10:18-24; col. 10:33-42; col. 10:43-50; col. 10:51-59; col. 10:60-67.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 2:16-35; col. 2:40-50; col. 3:8-12; col. 3:29-32; col. 3:33-49; col. 3:55-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); col. 7:29-32; col. 7:38-41; col. 10:57-64; col. 11:49-51; col. 11:65-12:13; col. 12:43-64; col. 13:13-19.

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p. 3:10-31 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); p. 4:2-12; p. 6:21-28 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be

subjected."); claim 1:1-14; claim 8:1-5; claim 10:1-3; claim 11:1-13; claim 22; claim 23:1-14; claim 19:4-31.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8.

Myler '563: Col. 2:10-13; col. 3:13-15; col. 3:52-54; col. 4:30-43 ("In a preferred embodiment, the interior and exterior walls of stent 10 are enclosed in a thin polymeric envelope. . . . Suitable envelope materials include elastic materials such as latex and others that can be readily selected by one of skill in the art."); col. 5:1-16; col. 5:39-41 ("For the above reasons, even the expanded pores for drug delivery should be small enough to maximize or prevent cell penetration, but large enough for drug delivery."); col. 12:11-13; col. 12:19-23; col. 12:28-33 ("Suitable materials include elastomeric polymers or natural rubber (latex). . . . Polymeric stents can be provided with relatively fluid impenetrable walls, or porous walls such as to allow drug delivery, as will be apparent to one of skill in the art."); col. 12:63-65 ("Suitable coating materials include elastic materials such as polyethylene or PET or other materials that can be readily selected by one of skill in the art."); col. 18:51-19:9; col. 19:18-30; col. 19:31-32; col. 19:61-63; col. 20:33-49; col. 20:51-57.

Palmaz '417: Col. 6:66-68; col. 11:3-14 ("Examples of a suitable biologically compatible coating would be porous polyurethane, Teflon™ or other conventional biologically inert plastic materials."); col. 11:26-31 ("Examples of biologically compatible coatings would include coatings made of absorbable polymers such as those used to manufacture absorbable sutures. Such absorbable polymers include polyglycoides, polyacoides, and copolymers thereof.").

Tice '330: Col. 3:20-33 ("Suitable wall forming materials include polystyrene, ethylcellulose, cellulose acetate, hydroxyl propylmethylcellulose phthalate, cellulose acetate, dibutylaminohydroxypropyl ether, polyvinylbutyral, polyvinyl formal, poly(meth)acrylic acid ester, polyvinylacetal-diethylamino acetate, 2-methyl-5-vinyl pyridine methacrylate-methacrylic acid copolymer, polycarbonate, polyesters, polypropylene, vinylchloride-vinylacetate copolymer, polysaccharides, glycerol distearate, and the like. A preferred group of polymeric wall forming materials includes those which are biodegradable such as aliphatic polyesters including polylactide, polyglycolide, polycaprolactone and copolymers thereof."); col. 8:38-51.

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); col. 3:7-18; col. 3:56-63; col. 4:31-34 ("The outer membrane surface is nonporous, while porous inner membrane surface allows for the diffusion therethrough of active factor 26."); col. 5:18-28 ("In a preferred embodiment of the invention, the outer surface of the membrane is impermeable to solutes of any size, while the inner membrane surface contains pores [that] enable the active factors to diffuse out of the membrane and into the lumen of the channel."); col. 6:17-22 ("The layering procedure allows deposition of an impermeable coat on the outer surface of the device, insuring that the active factors incorporated into the membrane

walls will be inhibited from diffusing through the external surface, and will diffuse only through the inner membrane surface into the lumen of the channel."); 6:54-61; col. 9:18-10:3.

Folkman '560: col. 2:43-68 ("A biocompatible plastically deformable polymer matrix . . . substantially impermeable to a macromolecule"); col. 3:18-23 ("The polymer matrixes, which are suitably used in the present invention, are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:36-51 ("Typical polymeric material suitable for forming the matrix . . . include . . . alkylene-vinyl acetate copolymers . . . crosslinked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:52-4:26 ("In the presently preferred embodiment the polymeric materials useful for forming the matrix are the ethylene vinyl ester copolymers of the general formula . . ."); col. 11:56-12:20.

Cohen '496: Col. 3:26-45 ("The polymer matrices . . . are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:65-4:39 ("In a presently preferred embodiment, the polymeric materials useful for forming the matrix are the ethylenevinyl ester copolymers of the general formula . . ."); col. 9:40-10:17; col. 10:18-32.

Schiraldi '243: Col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 1:58-60; col. 2:30-51; col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 9:36-55; col. 10:12-18.

Valentini '029: Abstract; col. 2:29-57 ("It has been discovered that the repair of severed or avulsed nerves can be greatly enhanced by the use of selectively permeable polymeric materials as nerve guidance channels. . . . The devices can be formed from various polymeric materials, such as acrylic copolymers, polyvinylidene fluoride or polyurethane isocyanate Preferable, the materials allow passage therethrough of solutes having a molecular weight of about 100,000 daltons or less. . . . The nerve guidance channels of the present invention are also preferably designed to retain nerve growth factors secreted at the anastomatic site or seeded therein, as well as retain any luminal matrix material placed inside the guidance channels.").

Greco '135: Col. 3:48-4:1 ("These devices will consist of organic polymers and/or metallic materials including: . . . polyethylene . . . elastomeric organosilicon polymers, such as polysiloxanes, e.g. Silastic ®").

Aebischer '627: Col. 3:57-4:3 ("The polymeric insert includes pores having a molecular weight exclusion of from about 1 kD to about 1,000 kD, but preferably from about 25kD to about 100 kD."); col. 4:11-27 ("The terms 'semipermeable' is used herein to describe biocompatible membranes that allow the diffusion therethrough of molecules having a relatively low molecular weight, while excluding the passage of those having a relatively high molecular weight. . . . The semipermeable membrane can be made of various polymeric compositions such as polyvinylchloride, polyacrylonitrile, polyvinylidene fluoride, polystyrene, polymethylmethacrylate, polysulfone, and acrylic copolymers."); col. 7:57-8:14 ("In this embodiment, a semi-permeable membrane functions as a protective cell culture device for the neurotransmitter-secreting cells. The pores of the membrane should be large enough to enable the exchange of metabolites with body fluids, and to permit the diffusion therethrough of neurotransmitter produced by the cells therein, but are small enough to bar the passage therethrough of larger elements deleterious to the cells."); col. 13:31-48; col. 13:66-68; col. 14:1-2; col. 14:22-28; col. 14:54-56.

Wood '066: Abstract ("A controlled-release bandage containing therapeutic agents in a poly(vinyl alcohol) cryogel is disclosed. The bandage may include . . . hydrophobic particles to further insure controlled and constant release of therapeutic agents."); col. 2:56-66; col. 23:4-11.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:63-2:2; col. 2:12-15 ("The present invention on the other hand exploits a wrapping material that plastically deforms as it expands . . ."); col. 2:21-38; col. 2:59-64; col. 3:7-16; col. 3:27-33 ("The lining can to advantage be made of polymers or compounds thereof."); col. 3:51-62; col. 3:51-62; col. 5:49-54 ("The thread itself in an endoprosthesis of the type illustrated in Fig. 3 can also be wrapped in a coat of medicated and biodegradable wrapping material. . . . The prosthesis can of course alternatively be enclosed in a flexible-tubular coat."); col. 6:50-55; col. 6:59-62; col. 7:16-35; col. 8:4-8; col. 8:19-10:19.

Lambert '246: Abstract ("Thus, a polyurethane coating is applied to a prosthetic article, the coating then swelled . . . so that substantial quantities of biologically active compounds can be incorporated within the interstices of the polymer."); col. 2:15-34; col. 2:40-49; col. 2:53-65; col. 3:55-4:35 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility to as to enable the application of a stable coating onto substrate (i.e. the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected)."); col. 10:45-67; col. 11:34-59; col. 12:15-41.

Bellamkonda '029: Abstract; col. 10:28-40; 12:13-16 ("Preferably the permselective membrane is fabricated to be impermeable to some of these substances so that they are retained in the proximity of the regenerating nerve ends.").

Dayton '382: Abstract ("The device comprises a stent which is formed from metal or polymers into a predetermined shape which includes a plurality of holes . . . to provide a desired bending modulus. The stent is then coated with a polymer . . . which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids, with the equilibrium being controlled by charge distribution, concentration and molecular weight of the bioactive substance in relation to the pore size of the polymeric carrier for controlled prolonged release of said bioactive substance."); col. 3:62-4:4:17 ("Among these polymers are polymers having a microporous structure, such as . . . biodegradable polylactic acid polymers, polyglycolic acid polymers . . ."); col. 4:24-33 ("A bioactive substance is preferably admixed in the polymer for elution from the microporous structure of the stent or coating on the stent after implantation. The rate of elution of the bioactive substance is controlled by selecting a pore size for microporous structure . . ."); col. 4: 42-50; col. 4:54-5:3; col. 6:64-7:7 ("The polymer should have a microporous structure with a predetermined pore size."); col. 8:19-33; col. 8:42-59; col. 8:66-9:5; col. 10:1-2.

Burt '036: p. 4:19-33 ("Similarly a wide variety of polymeric carriers may be utilized, representative examples of which include poly(ethylene-vinyl acetate) . . . and copolymers of polylactic acid and polycaprolactone."); p.10:17-25; p.14:9-27 ("As noted above, anti-angiogenic compositions of the present invention comprise an anti-angiogenic factor and a polymeric carrier. In addition to the wide array of anti-angiogenic factors and other compounds discussed above, anti-angiogenic compositions of the present invention may include a wide variety of polymeric carriers, including for example both biodegradable and non-biodegradable compositions."); p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size."); p.51:1-52:35.

Goldin '568: Col. 1:43-62 ("Release by controlled diffusion may be accomplished by means of containment of the therapeutic agent within a substrate whose small pore size and/or tortuosity of diffusion path thereof limits the diffusion of said agent through the substrate. . . . The therapeutic agent can be incorporated within the diffusion-limiting substrate Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:24-29 ("Microporous membranes for release of proteins by controlled diffusion have been fabricated from ethylene vinyl acetate (EVA), and said membranes have been used in vivo in a manner which demonstrates their therapeutic potential."); col. 5:28-34 (" . . . underlayment material of controlled pore size can be created and used to fabricate a device of optimal porosity . . . and accessibility of the releasable macromolecule to biological material at or beyond the membrane's external surface . . ."); Fig. 1A; col. 11:58-12:14; col. 13:53-65; col. 14:1-28; col. 14:66-15:67; col. 31:57-32:7 ("The device of claim 1 wherein said microporous underlayment comprises a polymer."); col. 32:16-22.

Palmaz '665: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3:47-51 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5: 30-32 ("FIGS. 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon."); Figures 5 and 6.

Palmaz '762: Col. 10:28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials."); col.3:65-4:2 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 9:20-25; col. 10:28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '337: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3:52-56 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5: 19-21; Figures 5 and 6; col. 8: 28-32; col. 9: 24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Aebischer: p. 283 (disclosing impermeable polymer layer that restricts passage of treating material).

Dev: p. 273 ("We used a commercially available biomedical grade polyurethane Tecoflex is a biocompatible, flexible, and an elastic membrane-forming polymer.").

Claim 5 [5A]: The device of claim 1 whereby the apposition of the device adjacent to the damaged tissue forms a chamber,

Where Found in the Prior References:

Schwartz '823: Abstract ("The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen."); Figs. 6-9, 13, 15; col. 2:37-40 ("In essence, this improvement makes it possible to provide a stent able to support body lumens and conform to

curves or irregularities in body lumens."); col. 2:44-54 ("The composite stent of the present invention can be delivered to the site of the occlusion by catheter and expanded conventionally, causing the film to expand or open radially along with the metallic elements of the stent and to be brought into contact with the body lumen. The polymeric film is flexible and preferably an elastic or stretchable film that is capable of conforming to the movement of the metallic stent elements when expanded into contact with a body lumen."); col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:48-54; col. 3:58-col. 4:6; col. 6:49-52 ("As shown in Fig. 13, the stent can be delivered to the body lumen and expanded (e.g. by use of a balloon catheter) into contact with the body lumen."); col. 6:33-37 ("As shown in Fig. 9, with the angioplasty procedure completed, balloon is deflated and withdrawn leaving stent firmly implanted within vessel with the film held in contact with the vessel."); col. 6:62-68 ("Once in the desired location, the stent can be released from the catheter and expanded into contact with the lumen as shown in Fig. 15 where it can conform to the curvature of the body lumen. The flexible film is able to form folds which allow the stent elements to readily adapt to the curvature of the body lumen.").

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14 ("The present invention satisfies this need by providing a separate sleeve to encompass the stent and serve as a local drug delivery device to prevent thrombosis."); col. 4:53-55 ("The present invention satisfies this need by providing a separate sleeve to encompass a stent to locally administer drugs to prevent restenosis."); col. 4:58-68 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. . . . Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 5:26-29; col. 6:49-55 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface); col. 8:8-22; col. 8:58-60 ("The films were placed to line the circumference of a 2 cm length of ePTFE grafts, over which a 2 cm long stent was deployed."); col. 9:12-16 ("In addition, polymer-drug films which

prevent thrombosis in the baboon and pig AV shunt system can be studied following stent-film placement in carotid, superficial femoral and coronary arteries following balloon injury of those vessels."); col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Fig. 8; col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:12-20 ("Stents are typically implanted within a vessel in a contracted state and expanded when in place in the vessel in order to maintain patency of the vessel to allow fluid flow through the vessel. Ideally, the implantation of such stents is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:50-56 ("The stent can be used in coronary arteries or any other part of the vasculature or other body lumen where mechanical opening force is necessary or desirable to keep the vessel open or to maintain the stent flush against the lumen wall, and where an anti-restenosis, anti-proliferative or other types of therapeutic drug or agent is to be simultaneously positioned and diffused."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 2:23-33; col. 5:15-17; col. 7:56-62; col. 9:63-67 ("The deployment of the stent can also be improved by . . . decreasing friction between the vessel or lumen wall and the stent."); col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:52-54 ("The invention provides prostheses which may be inserted into a lumen of a body and fixed to the

lumen wall adjacent an area needing treatment."); col. 1:63-66 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery."); col. 2:7-9 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:25-27 ("The current invention contemplates the usage of any prosthesis which elutes drugs locally to treat a lumen in need of repair."); col. 6:36-38; col. 6:56-58 ("The stent shown in Figs. 2 and 4 is a metallic malleable design which may be forced against a lumen wall by a balloon catheter which fixes it into position."); col. 6:64-67 ("The variations of design shown in the embodiments of Figs. 1 and 2 show that the prosthesis of the invention must be secured against a lumen wall and must carry a drug-eluting polymer."); col. 9:67-10:3 ("By including a metal stent within the lumen of the polymeric prosthesis, the polymeric prosthesis is effectively held against the wall of the body lumen by the strength of the metal stent."); col. 10:23-38 ("The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen. This will bring the bioabsorbable element into supporting contact with a body lumen at an interior position of the body lumen to be treated and will position the bioabsorbable element to deliver drugs to the body lumen. Following the expansion of the stents into luminal contact, the balloon (if the expansion device is a balloon) can be deflated which allows the luminal flow to be restored."); col. 10:46-59; col. 11:10-13; col. 11:17-20; col. 11:50-53 ((b) a body including a plurality of support elements forming an open-ended, radially expandable, self-supporting tubular structuring having an interior surface and an exterior surface."); col. 12:1-15.

Berg '354: Page 2:14-18 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen. Examples of stents which have been successfully applied over a PTCA balloon and radially expanded at the same time as the balloon expansion of an affected artery include the stents disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) which are incorporated herein by reference in their entirety."); p. 2:34-36 ("Metal stents such as those disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) could be suitable for drug delivery in that they are capable of maintaining intimate contact between a substance applied to the outer surface of the stent and the tissues of the vessel to be treated."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:16-18 ("In operation, the stent made according to the present invention can deliver drugs to a body lumen by introducing the stent transluminally into a selected portion of the body lumen and radially expanding the stent into contact with the body lumen.").

Buscemi '450: Col. 3:14-15 ("The stent strengthens an area of the vessel that is in contact with the stent."); col. 3:21-25 ("The tubular main body includes an outer surface and inner surface. The outer surface of the main body faces an inner surface wall of the vessel. The inner

surface of the stent faces a stream flowing through the lumen as shown in cross section in Fig. 2."); col. 4:61-64 ("The stent is secured by releasing the stent from compression so that the stent can radially spring out to abut against the inner surface wall of the vessel."); col. 6:49-52; col. 7:27-29; col. 8:9-11.

Ding '536: Col. 5:38-40 ("Surface material should minimize tissue rejection and tissue inflammation and permit encapsulation by tissue adjacent the stent implantation site.").

Dinh '227: Col. 1:32-35 ("The stent is typically inserted by catheter into a vascular lumen told [sic] expanded into contact with the diseased portion of the arterial wall, thereby providing mechanical support for the lumen."); col. 8:20-23 ("The term "stent" herein means any device which when placed into contact with a site in the wall of a lumen to be treated, will also place fibrin at the lumen wall and retain it at the lumen wall."); col. 8:37-43; col. 9:18-24 ("The stent is then delivered through the body lumen on the catheter to the treatment site where the stent is released from the catheter to allow it to expand into contact with the lumen wall.").

Domb '055: Abstract ("Preferred embodiments include catheters, tubes, and implants that abut tissue following implantation into the body . . ."); col. 4:25-32; col. 5:27-33; col. 5:49-54; col. 5:63-6:1 ("Coating that part of the tube, which is in contact with the mucosa, with the drug-loaded polymer provides a sustained release of steroids and antibiotics locally and at high concentration in the area which is critically affected, achieving the same effect as the systemic administration of the drugs without their side effects, throughout the duration of the intubation."); col. 6:8-18; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages.").

Kowligi '782: Abstract; col. 1:18-41; Figs. 2, 3; col. 10:18-67.

Hunter '981: Col. 4:24-38; col. 5:1-6; col. 16:31-56; col. 22:3-7; col. 22:54-58; col. 23:6-13 ("[M]ethods are provided for expanding the lumen of a body passageway, comprising inserting a stent into the passageway, the stent having a generally tubular structure, the surface of the structure being coated with an anti-angiogenic composition . . . such that the passageway is expanded."); col. 23:30-31; col. 23:46-51; col. 24:45-51; col. 24:66-25:5; col. 25:24-29; col. 25:48-54; col. 52:4-8 ("This film is designed to be placed on exposed tissue so that any encapsulated drug is released from the polymer over a long period of time at the tissue site."); 86:56-59; col. 87:11-22; col. 88:19-26.

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Myler '563: Col. 3:34-37 ("Stent 10 is illustrated in its expanded position at a treatment location adjacent vascular wall in an artery, in accordance with one aspect of the present invention."); col. 4:53-56 ("The exterior surface of the envelope which will contact the arterial wall is optionally made porous to enable the release of drugs from the envelope and/or stent to the treatment site."); col. 10:12-14 ("The balloon is inflated, thereby expanding the stent radially outwardly until it contacts either a previously dilated, or presently stenosed wall."); col. 10:56-61; col. 11:63-65 ("Once the stent has been positioned at the treatment site, axial elongating tension is released, and it is permitted to radially expand against the lumen wall."); col. 13:15-17 ("The exterior coating which will contact the arterial wall is optionally made porous to enable the release of drugs to the treatment site.").

Palmaz '417: col. 4:25-37 (" . . . expanding a portion of the catheter associated with the prostheses to force at least one of the prostheses radially outward into contact with the body passageway . . .").

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); Figs. 1 and 2; col. 9:18-10:3.

Strecker '746: Figs. 7 & 8.

Schiraldi '243: Col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Valentini '029: Col. 2:39-41 ("The tubular membrane defines a lumen through which axons can be regenerated to restore motor and/or sensory functions."); Figure 3; col. 2:32-35 ("Medical devices employing such selectively permeable materials, particularly semipermeable tubular devices having smooth inner skins, are disclosed for use in regenerating nerves.").

Bawa '279: Col. 6:40-44; col. 12:29-34.

Wood '066: Col. 2:67-3:32 ("The object of this invention is to provide means for delivery effective dosages of therapeutic agents to sites of trauma such as wounds, thermal or chemical burns, ulcers, lesions, or surgical sites.").

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Burt '036: p.14:9-27; p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size.").

Goldin '568: Figs. 5A-5F; col. 9:7-12 (" . . . a substance that, when implanted in or juxtaposed against a living body . . ."); col. 22:46-23:3.

Palmaz '665: Col 8:59-64 ("Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80."); col. 5: 25-29; Figure 4.

Palmaz '762: col. 4: 14-19 (...expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway..."); col. 4: 53-56; col. 5: 43-45; col. 9: 1-6; col 9:68-10:10 ("Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80."); Figure 4.

Palmaz '337: Col. 3:60-4:2 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into a body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded, whereby the intraluminal graft prevents the body passageway from collapsing and decreasing the size of the expanded lumen."); col. 4: 36-40; col. 5: 32-34; col. 7: 28-36; col. 8: 17-22; col. 8:67-9:8 ("Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80."); Figure 4.

Claim 5 [5B]: one wall of the chamber being formed by the layer,

Where Found in the Prior References:

Schwartz '823: Abstract ("The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen."); Figs. 6-9, 13, 15; col. 2:37-40 ("In essence, this improvement makes it possible to provide a stent able to support body lumens and conform to curves or irregularities in body lumens."); col. 2:44-54 ("The composite stent of the present invention can be delivered to the site of the occlusion by catheter and expanded conventionally, causing the film to expand or open radially along with the metallic elements of the stent and to be brought into contact with the body lumen. The polymeric film is flexible and preferably an elastic or stretchable film that is capable of conforming to the movement of the metallic stent elements when expanded into contact with a body lumen."); col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:48-54; col. 3:58-col. 4:6; col. 6:49-52 ("As shown in Fig. 13, the stent can be delivered to the body lumen and expanded (e.g. by use of a balloon

catheter) into contact with the body lumen."); col. 6:33-37 ("As shown in Fig. 9, with the angioplasty procedure completed, balloon is deflated and withdrawn leaving stent firmly implanted within vessel with the film held in contact with the vessel."); col. 6:62-68 ("Once in the desired location, the stent can be released from the catheter and expanded into contact with the lumen as shown in Fig. 15 where it can conform to the curvature of the body lumen. The flexible film is able to form folds which allow the stent elements to readily adapt to the curvature of the body lumen.").

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14 ("The present invention satisfies this need by providing a separate sleeve to encompass the stent and serve as a local drug delivery device to prevent thrombosis."); col. 4:53-55 ("The present invention satisfies this need by providing a separate sleeve to encompass a stent to locally administer drugs to prevent restenosis."); col. 4:58-68 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. . . . Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 5:26-29; col. 6:49-55 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface); col. 8:8-22; col. 8:58-60 ("The films were placed to line the circumference of a 2 cm length of ePTFE grafts, over which a 2 cm long stent was deployed."); col. 9:12-16 ("In addition, polymer-drug films which prevent thrombosis in the baboon and pig AV shunt system can be studied following stent-film placement in carotid, superficial femoral and coronary arteries following balloon injury of those vessels."); col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Fig. 8; col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:12-20 ("Stents are typically implanted within a vessel in a contracted state and expanded when in place in the vessel in order to maintain patency of the vessel to allow fluid flow through the vessel. Ideally, the implantation of such stents is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:50-56 ("The stent can be used in coronary arteries or any other part of the vasculature or other body lumen where mechanical opening force is necessary or desirable to keep the vessel open or to maintain the stent flush against the lumen wall, and where an anti-restenosis, anti-proliferative or other types of therapeutic drug or agent is to be simultaneously positioned and diffused."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 2:23-33; col. 5:15-17; col. 7:56-62; col. 9:63-67 ("The deployment of the stent can also be improved by . . . decreasing friction between the vessel or lumen wall and the stent."); col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:52-54 ("The invention provides prostheses which may be inserted into a lumen of a body and fixed to the lumen wall adjacent an area needing treatment."); col. 1:63-66 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery."); col. 2:7-9 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:25-27 ("The current invention contemplates the usage of any prosthesis which elutes drugs locally to treat a lumen in need of repair."); col. 6:36-38; col. 6:56-58 ("The stent shown in Figs. 2 and 4 is a metallic malleable design which may be forced against a lumen wall by a balloon catheter which fixes it into position."); col. 6:64-67 ("The variations of design shown in the embodiments of Figs. 1 and 2 show that the prosthesis of the invention must be secured against a lumen wall and must carry a drug-eluting polymer."); col. 9:67-10:3 ("By including a metal stent within the lumen of the polymeric prosthesis, the polymeric prosthesis is effectively held against the wall of the body lumen by the strength of the metal stent."); col.

10:23-38 ("The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen. This will bring the bioabsorbable element into supporting contact with a body lumen at an interior position of the body lumen to be treated and will position the bioabsorbable element to deliver drugs to the body lumen. Following the expansion of the stents into luminal contact, the balloon (if the expansion device is a balloon) can be deflated which allows the luminal flow to be restored."); col. 10:46-59; col. 11:10-13; col. 11:17-20; col. 11:50-53 ((b) a body including a plurality of support elements forming an open-ended, radially expandable, self-supporting tubular structuring having an interior surface and an exterior surface."); col. 12:1-15.

Berg '354: Page 2:14-18 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen. Examples of stents which have been successfully applied over a PTCA balloon and radially expanded at the same time as the balloon expansion of an affected artery include the stents disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) which are incorporated herein by reference in their entirety."); p. 2:34-36 ("Metal stents such as those disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) could be suitable for drug delivery in that they are capable of maintaining intimate contact between a substance applied to the outer surface of the stent and the tissues of the vessel to be treated."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:16-18 ("In operation, the stent made according to the present invention can deliver drugs to a body lumen by introducing the stent transluminally into a selected portion of the body lumen and radially expanding the stent into contact with the body lumen.").

Buscemi '450: Col. 3:14-15 ("The stent strengthens an area of the vessel that is in contact with the stent."); col. 3:21-25 ("The tubular main body includes an outer surface and inner surface. The outer surface of the main body faces an inner surface wall of the vessel. The inner surface of the stent faces a stream flowing through the lumen as shown in cross section in Fig. 2."); col. 4:61-64 ("The stent is secured by releasing the stent from compression so that the stent can radially spring out to abut against the inner surface wall of the vessel."); col. 6:49-52; col. 7:27-29; col. 8:9-11.

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Goldin '568: Figs. 5A-5F; col. 9:7-12 (" . . . a substance that, when implanted in or juxtaposed against a living body . . ."); col. 22:46-23:3.

Palmaz '665: Col 8:59-64 ("Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80."); col. 5: 25-29; Figure 4.

Palmaz '762: col. 4: 14-19 (...expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway..."); col. 4: 53-56; col. 5: 43-45; col. 9: 1-6; col 9:68-10:10 ("Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80."); Figure 4.

Palmaz '337: Col. 3:60-4:2 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into a body passageway until it is

disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded, whereby the intraluminal graft prevents the body passageway from collapsing and decreasing the size of the expanded lumen."); col. 4: 36-40; col. 5: 32-34; col. 7: 28-36; col. 8: 17-22; col. 8:67-9:8 ("Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80."); Figure 4.

Claim 5 [5C]: one wall of the chamber being formed by the damaged tissue,

Where Found in the Prior References:

Schwartz '823: Abstract ("The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen."); Figs. 6-9, 13, 15; col. 2:37-40 ("In essence, this improvement makes it possible to provide a stent able to support body lumens and conform to curves or irregularities in body lumens."); col. 2:44-54 ("The composite stent of the present invention can be delivered to the site of the occlusion by catheter and expanded conventionally, causing the film to expand or open radially along with the metallic elements of the stent and to be brought into contact with the body lumen. The polymeric film is flexible and preferably an elastic or stretchable film that is capable of conforming to the movement of the metallic stent elements when expanded into contact with a body lumen."); col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:48-54; col. 3:58-col. 4:6; col. 6:49-52 ("As shown in Fig. 13, the stent can be delivered to the body lumen and expanded (e.g. by use of a balloon catheter) into contact with the body lumen."); col. 6:33-37 ("As shown in Fig. 9, with the angioplasty procedure completed, balloon is deflated and withdrawn leaving stent firmly implanted within vessel with the film held in contact with the vessel."); col. 6:62-68 ("Once in the desired location, the stent can be released from the catheter and expanded into contact with the lumen as shown in Fig. 15 where it can conform to the curvature of the body lumen. The flexible film is able to form folds which allow the stent elements to readily adapt to the curvature of the body lumen.").

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has

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been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14 ("The present invention satisfies this need by providing a separate sleeve to encompass the stent and serve as a local drug delivery device to prevent thrombosis."); col. 4:53-55 ("The present invention satisfies this need by providing a separate sleeve to encompass a stent to locally administer drugs to prevent restenosis."); col. 4:58-68 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. . . . Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 5:26-29; col. 6:49-55 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface); col. 8:8-22; col. 8:58-60 ("The films were placed to line the circumference of a 2 cm length of ePTFE grafts, over which a 2 cm long stent was deployed."); col. 9:12-16 ("In addition, polymer-drug films which prevent thrombosis in the baboon and pig AV shunt system can be studied following stent-film placement in carotid, superficial femoral and coronary arteries following balloon injury of those vessels."); col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Fig. 8; col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:12-20 ("Stents are typically implanted within a vessel in a contracted state and expanded when in place in the vessel in order to maintain patency of the vessel to allow fluid flow through the vessel. Ideally, the implantation of such stents is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by

inflation of a balloon within the stent."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:50-56 ("The stent can be used in coronary arteries or any other part of the vasculature or other body lumen where mechanical opening force is necessary or desirable to keep the vessel open or to maintain the stent flush against the lumen wall, and where an anti-restenosis, anti-proliferative or other types of therapeutic drug or agent is to be simultaneously positioned and diffused."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 2:23-33; col. 5:15-17; col. 7:56-62; col. 9:63-67 ("The deployment of the stent can also be improved by . . . decreasing friction between the vessel or lumen wall and the stent."); col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:52-54 ("The invention provides prostheses which may be inserted into a lumen of a body and fixed to the lumen wall adjacent an area needing treatment."); col. 1:63-66 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery."); col. 2:7-9 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:25-27 ("The current invention contemplates the usage of any prosthesis which elutes drugs locally to treat a lumen in need of repair."); col. 6:36-38; col. 6:56-58 ("The stent shown in Figs. 2 and 4 is a metallic malleable design which may be forced against a lumen wall by a balloon catheter which fixes it into position."); col. 6:64-67 ("The variations of design shown in the embodiments of Figs. 1 and 2 show that the prosthesis of the invention must be secured against a lumen wall and must carry a drug-eluting polymer."); col. 9:67-10:3 ("By including a metal stent within the lumen of the polymeric prosthesis, the polymeric prosthesis is effectively held against the wall of the body lumen by the strength of the metal stent."); col. 10:23-38 ("The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen. This will bring the bioabsorbable element into supporting contact with a body lumen at an interior position of the body lumen to be treated and will position the bioabsorbable element to deliver drugs to the body lumen. Following the expansion of the stents into luminal contact, the balloon (if the expansion device is a balloon) can be deflated which allows the luminal flow to be restored."); col. 10:46-59; col. 11:10-13; col. 11:17-20; col. 11:50-53 ((b) a

body including a plurality of support elements forming an open-ended, radially expandable, self-supporting tubular structuring having an interior surface and an exterior surface."); col. 12:1-15.

Berg '354: Page 2:14-18 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen. Examples of stents which have been successfully applied over a PTCA balloon and radially expanded at the same time as the balloon expansion of an affected artery include the stents disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) which are incorporated herein by reference in their entirety."); p. 2:34-36 ("Metal stents such as those disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) could be suitable for drug delivery in that they are capable of maintaining intimate contact between a substance applied to the outer surface of the stent and the tissues of the vessel to be treated."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:16-18 ("In operation, the stent made according to the present invention can deliver drugs to a body lumen by introducing the stent transluminally into a selected portion of the body lumen and radially expanding the stent into contact with the body lumen.").

Buscemi '450: Col. 3:14-15 ("The stent strengthens an area of the vessel that is in contact with the stent."); col. 3:21-25 ("The tubular main body includes an outer surface and inner surface. The outer surface of the main body faces an inner surface wall of the vessel. The inner surface of the stent faces a stream flowing through the lumen as shown in cross section in Fig. 2."); col. 4:61-64 ("The stent is secured by releasing the stent from compression so that the stent can radially spring out to abut against the inner surface wall of the vessel."); col. 6:49-52; col. 7:27-29; col. 8:9-11.

Ding '536: Col. 5:38-40 ("Surface material should minimize tissue rejection and tissue inflammation and permit encapsulation by tissue adjacent the stent implantation site.").

Dinh '227: Col. 1:32-35 ("The stent is typically inserted by catheter into a vascular lumen told [sic] expanded into contact with the diseased portion of the arterial wall, thereby providing mechanical support for the lumen."); col. 8:20-23 ("The term "stent" herein means any device which when placed into contact with a site in the wall of a lumen to be treated, will also place fibrin at the lumen wall and retain it at the lumen wall."); col. 8:37-43; col. 9:18-24 ("The stent is then delivered through the body lumen on the catheter to the treatment site where the stent is released from the catheter to allow it to expand into contact with the lumen wall.").

Domb '055: Abstract ("Preferred embodiments include catheters, tubes, and implants that abut tissue following implantation into the body . . ."); col. 4:25-32; col. 5:27-33; col. 5:49-54; col. 5:63-6:1 ("Coating that part of the tube, which is in contact with the mucosa, with the drug-loaded polymer provides a sustained release of steroids and antibiotics locally and at high concentration in the area which is critically affected, achieving the same effect as the systemic administration of the drugs without their side effects, throughout the duration of the

intubation."); col. 6:8-18; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages.").

Kowligi '782: Abstract; col. 1:18-41; Figs. 2, 3; col. 10:18-67.

Hunter '981: Col. 4:24-38; col. 5:1-6; col. 16:31-56; col. 22:3-7; col. 22:54-58; col. 23:6-13 ("[M]ethods are provided for expanding the lumen of a body passageway, comprising inserting a stent into the passageway, the stent having a generally tubular structure, the surface of the structure being coated with an anti-angiogenic composition . . . such that the passageway is expanded."); col. 23:30-31; col. 23:46-51; col. 24:45-51; col. 24:66-25:5; col. 25:24-29; col. 25:48-54; col. 52:4-8 ("This film is designed to be placed on exposed tissue so that any encapsulated drug is released from the polymer over a long period of time at the tissue site."); 86:56-59; col. 87:11-22; col. 88:19-26.

Lambert '922: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion."); col. 3:54-61; col. 8:1-6.

Lambert '308: Page 3:24-27 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion.").

Myler '563: Col. 3:34-37 ("Stent 10 is illustrated in its expanded position at a treatment location adjacent vascular wall in an artery, in accordance with one aspect of the present invention."); col. 4:53-56 ("The exterior surface of the envelope which will contact the arterial wall is optionally made porous to enable the release of drugs from the envelope and/or stent to the treatment site."); col. 10:12-14 ("The balloon is inflated, thereby expanding the stent radially outwardly until it contacts either a previously dilated, or presently stenosed wall."); col. 10:56-61; col. 11:63-65 ("Once the stent has been positioned at the treatment site, axial elongating tension is released, and it is permitted to radially expand against the lumen wall."); col. 13:15-17 ("The exterior coating which will contact the arterial wall is optionally made porous to enable the release of drugs to the treatment site.").

Palmaz '417: col. 4:25-37 (" . . . expanding a portion of the catheter associated with the prostheses to force at least one of the prostheses radially outward into contact with the body passageway . . .").

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); Figs. 1 and 2; col. 9:18-10:3.

Strecker '746: Figs. 7 & 8.

Schiraldi '243: Col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consist of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Valentini '029: Col. 2:39-41 ("The tubular membrane defines a lumen through which axons can be regenerated to restore motor and/or sensory functions."); Figure 3; col. 2:32-35 ("Medical devices employing such selectively permeable materials, particularly semipermeable tubular devices having smooth inner skins, are disclosed for use in regenerating nerves.").

Bawa '279: Col. 6:40-44; col. 12:29-34.

Wood '066: Col. 2:67-3:32 ("The object of this invention is to provide means for delivery effective dosages of therapeutic agents to sites of trauma such as wounds, thermal or chemical burns, ulcers, lesions, or surgical sites.").

Aebischer '486: Fig. 1.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:63-2:2; col. 2:21-32; col. 2:33-38; col. 2:39-46; col. 3:63-4:31 ("It can be of advantage for the lining to be of several layers, each impregnated with different medications. . . . It has also been demonstrated practical for the inner layer of the lining to be impregnated with antithrombotics and the outer with antiproliferatives and/or other medicational substances."); Fig. 4; col. 5:18-20 ("Fig. 4 is a view similar to that of Fig. 2 of an endoprosthesis with a multiple-layer lining and with its ends coated with medication,"); col. 5:34-41 ("The endoprosthesis . . . is completely enclosed in an inner lining component and an outer lining component."); Fig. 7; col. 6:30-44 ("The endoprosthesis 40 in the embodiment illustrated in Fig. 7 comprises a lining 42 and 43 in the form of a double walled sleeve. The outer lining component 43 of the in-place and expanded

stent rests against the inner surface 46 of the blood vessel. Inner lining component 42 rests against the stent."); col. 7:16-35; col. 7:48-65; col. 8:19-10:19.

Lambert '246: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion.").

Bellamkonda '029: Fig. 6.

Dayton '382: Abstract ("The stent is then coated with a polymer or is formed from a polymer which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids . . ."); col. 4:4-10; col. 6:64-7:7; col. 8:18-19 ("a polymer forming the exterior surface of said stent for operative contact with said tissue . . .").

Burt '036: p.14:9-27; p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size.").

Goldin '568: Figs. 5A-5F; col. 9:7-12 (" . . . a substance that, when implanted in or juxtaposed against a living body . . ."); col. 22:46-23:3.

Palmaz '665: Col 8:59-64 ("Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80."); col. 5: 25-29; Figure 4.

Palmaz '762: col. 4: 14-19 (...expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway..."); col. 4: 53-56; col. 5: 43-45; col. 9: 1-6; col 9:68-10:10 ("Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80."); Figure 4.

Palmaz '337: Col. 3:60-4:2 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into a body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded, whereby the intraluminal graft prevents the body passageway from collapsing and decreasing the size of the expanded lumen."); col. 4: 36-40; col. 5: 32-34; col. 7: 28-36; col. 8: 17-22; col. 8:67-9:8 ("Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80."); Figure 4.

Claim 5 [5D]: such that the formed chamber contains a lower concentration of at least one type of macromolecule compared to outside the chamber.

Where Found in the Prior References:

Schwartz '823: Abstract; col. 2:29-40; col. 2:49-53; col. 3:58-61 ("The improvement of the present invention includes applying to the above-mentioned type of stent a flexible or elastomeric polymeric film which extends between the metal elements."); col. 3:64-4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof."); col. 6:17-20; col. 7:25-8:11.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); Fig. 3; col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-33; col. 5:34-6:29; col. 6:37-41; col. 6:41-45 ("Modifications of the polymer coating include a ring that encompasses the proximal portion of the stent, single or multiple strips that cover a portion of the stent, or a polymer coating with perforations."); col. 8:23-25 ("Ethylene vinyl acetate copolymer (EVA) (Catalog #34,691-8) was obtained from Aldrich Chemical Company, Inc. (Milwaukee, Wis.); col. 10:24-33; col. 12:1-6; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow Controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Col. 1:7-10 ("This invention relates generally to expandable intraliminal vascular grafts,

generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 1:64-2:2 ("The polymer material can be a thermoplastic or an elastomer, for example, so that the film can stretch or deform radially when the stent structural member is expanded. The film of polymer material can be formed as a solid sheet, or can incorporate holes of various sizes and shapes to promote rapid endothelialization."); col. 4:15-24; col. 4:25-46; col. 4:47-5:3; col. 5:4-9; col. 5:49- 6:25 ("The polymeric material is preferably selected from thermoplastic and elastomeric polymers. . . . In another currently preferred embodiment, the polymeric material can be ethylene vinyl acetate (EVA) . . ."); col. 6:26-65; col. 7:23-42; col. 7:63-65; col. 8:12-57; col. 9:5-12; col. 10:12-30.

Wolff '208: Col. 2:7-16 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:28-30 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 6:59-62 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously. The polymer may be biostable or bioabsorbable. If biostable, the drug would diffuse out of the polymer."); col. 6:64-67; col. 7:59-61; col. 9:23-33 ("That layer may be a simple barrier which limits diffusion of drugs in the polymer. In that event, the smaller molecules could elute out immediately, while larger compounds would not elute until later when the layer has biodegraded."); col. 12:37-40 ("8. The device of claim 1 also comprising a barrier coating of polymeric material on the drug-containing filament to limit the rate of drug elution.").

Berg '354: Page 2:43-54 ("Viewed from a further aspect the invention provides the use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug-eluting surface coating."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:29-31 ("Also, stents made with biostable or bioabsorbable polymers such as poly(ethylene terephthalate), polyacetal, poly(lactic acid), poly(ethylene oxide)/poly(butylene terephthalate) copolymer could be used in the present invention. "); Table 1; p. 4:5-24; p. 6:6-11; p. 6:15; p. 6:24-35; p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Abstract ("A stent made of biodegradable material includes a drug that is released at a rate controlled by the rate of degradation of the biodegradable material."); col. 2:16-17; col. 4:1-5 ("In one embodiment, the main body includes a film that is preferable combined with the plurality of fibers disposed around the main body. The film combined with the plurality of fibers defines the outer surface of the main body."); col. 4:15-16 ("Preferable, the main body of the stent includes a film covering the inner surface."); col. 4:19-22.

Ding '536: Abstract ("The coating includes a relatively thin layer of biostable elastomeric material containing an amount of biologically active material, particularly heparin, dispersed in the coating in combination with a non-thrombogenic surface."); col. 1:24-29 ("The present invention relates generally to providing biostable elastomeric coatings on the surfaces of implants which incorporate biologically active species having controlled release characteristics in the coating particularly to providing a non-thrombogenic surface during and after timed release of the biologically active species."); col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 5:10-56 ("Polymers generally suitable for the undercoats or underlayers include silicones (e.g., polysiloxanes and substituted polysiloxanes), polyurethanes, thermoplastic elastomers in general, ethylene vinyl acetate copolymers, polyolefin elastomers, polyamide elastomers, and EPDM rubbers. The above-referenced materials are considered hydrophobic with respect to the contemplated environment of the invention."); col. 12:62-13:2; col. 13:13-26; col. 13:37-40; col. 14:5-17; col. 14:22-34.

Dinh '227: Col. 2:51-54 ("To accomplish this while not affecting the strength of the overall fibrin stent structure, a first layer is applied to a stent body, the first layer incorporating a polymer and the therapeutic substance."); col. 2:62-66 ("The inclusion of a polymer in intimate contact with a drug on the underlying stent structure allows the drug to be retained on the stent in a resilient matrix during expansion of the stent and also slows the administration of drug following implantation."); col. 3:10-14; col. 3:25-38; col. 5:3-7; col. 5:44-55; col. 5:56-57; col. 6:13-19 ("In U.S. Pat. No. 4,548,736 issued to Muller et al., a dense fibrin composition is disclosed which can be a bioabsorbable matrix for delivery of drugs to a patient. Such a fibrin composition can also be used in the present invention by incorporating a drug or other therapeutic substance useful in diagnosis or treatment of body lumens to the fibrin provided on the stent."); 6:50-56 ("Alternatively . . . a dense fibrin composition suitable for drug delivery can be made without the use of microcapsules by adding the drug directly to the fibrin followed by compression of the fibrin into a sufficiently dense matrix that a desired elution rate for the drug is achieved."); col. 6:62-67; col. 7:10-13; col. 7:56-64 ("In another embodiment of the invention, the coating of polymer and drug on the stent is achieved by forming a first fibrin layer on the stent body which incorporates the therapeutic substance and then applying a second layer of fibrin."); col. 8:52-60 ("Fig. 2 shows an alternative stent in which a fibrin film has been affixed to the underlying metallic framework by affixing it to the stent . . ."); col. 8:64-9:3; col. 12:24-28; col. 12:38-50.

Domb '055: Abstract ("Devices are provided having a polymer coating incorporating compounds inhibiting inflammation and infection, along with subsequent tissue growth onto and

around the device. . . . Preferred polymeric coating are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); col. 1:12-15 ("This invention relates to invasive medical devices for delayed/sustained release of pharmaceutical compositions from a polymer that is coated or incorporated into the devices."); col. 3:54-57 ("In the preferred embodiments, these have utilized bioerodible polymers as the matrix for the drug to be released, usually as a function of diffusion and erosion of the polymer."); col. 4:22-36; col. 5:24-37; col. 5:41-45; col. 5:48-6:1; col. 6:24-26 ("Examples of suitable polymers include ethylene vinyl acetate, polyurethane, silicones, hydrogels, polyurethane, and polyvinyl chloride."); col. 7:10-20; col. 7:40-52; col. 9:15-30; col. 9:55-10:2; col. 10:21-52; col. 10:60-11:11; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 11:36-38 ("The medical device of claim 1, wherein the polymer is selected from the group consisting of polyurethane, ethylene vinyl acetate, silicones, hydrogels, and polyvinyl chloride."); col. 11:39-44; col. 12:11-22; col. 12:23-25; col. 12:26-31; col. 12:32-42.

Fox '096: Abstract ("A method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers, and antimicrobial agents . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 2:48-65; col. 3:55-67 ("The polymeric coating agent component of the coating vehicle of the present invention is selected from the group consisting of biomedical polyurethanes, biomedical silicones, biodegradable polymers and combinations thereof."); col. 19:11-16; col. 31:62-64.

Hunter '981: Col. 1:12-17; col. 3:42-45 ("Within one aspect of the present invention, compositions are provided (anti-angiogenic compositions) comprising (a) an anti-angiogenic factor and (b) a polymeric carrier."); col. 3:53-61; col. 12:23-25 ("As noted above, the present invention provides compositions comprising an anti-angiogenic factor, and a polymeric carrier."); col. 16:31-56; col. 17:63-18:7 ("[T]he anti-angiogenic compositions of the present invention may be formed as a film. . . . Such films are preferably flexible with a good tensile strength . . . and has controlled permeability."); col. 22:3-7; col. 22:54-58; col. 47:58-49:7; col. 52:4-8; col. 69:19-62; col. 84:62-86:24; 86:56-59; col. 87:11-22; col. 88:19-26.

Kowligi '782: Abstract ("The elastomeric coating is made of polyurethane or another biocompatible non-porous elastomers and precludes tissue ingrowth into the outer cylindrical wall, minimizes suture hold bleeding, and increases suture retention strength, while reducing the

incidence of serous weepage."); col. 1:18-26; col. 2:15-20; col. 2:38-47; col. 2:53-59; col. 3:27-37; Fig. 1; Fig. 2; Fig. 3; col. 2:60-67 ("PTFE tube 32 includes an inner cylindrical wall and an opposing outer cylindrical wall. As shown in Fig. 2, outer cylindrical wall 36 is coated entirely around its circumference by a uniformly thick coating of a biocompatible elastomer."); col. 3:27-38; col. 4:16-27 ("In regard to elastomeric coating 38 shown in Fig. 2, such elastomeric coating is selected to be a biocompatible elastomers and may be selected from the group consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 4:37-39 ("The elastomeric coating should also be sufficiently non-porous to preclude serous weepage and inhibit tissue ingrowth therethrough."); col. 5:4-7; col. 7:49-8:9; col. 8:38-44; col. 9:65-10:6; col. 10:18-24; col. 10:33-42; col. 10:43-50; col. 10:51-59; col. 10:60-67.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 2:16-35; col. 2:40-50; col. 3:8-12; col. 3:29-32; col. 3:33-49; col. 3:55-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); col. 7:29-32; col. 7:38-41; col. 10:57-64; col. 11:49-51; col. 11:65-12:13; col. 12:43-64; col. 13:13-19.

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p. 3:10-31 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); p. 4:2-12; p. 6:21-28 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); claim 1:1-14; claim 8:1-5; claim 10:1-3; claim 11:1-13; claim 22; claim 23:1-14; claim 19:4-31.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8.

Myler '563: Col. 2:10-13; col. 3:13-15; col. 3:52-54; col. 4:30-43 ("In a preferred embodiment, the interior and exterior walls of stent 10 are enclosed in a thin polymeric envelope. . . . Suitable envelope materials include elastic materials such as latex and others that can be readily selected by one of skill in the art."); col. 5:1-16; col. 5:39-41 ("For the above reasons,

even the expanded pores for drug delivery should be small enough to maximize or prevent cell penetration, but large enough for drug delivery."); col. 12:11-13; col. 12:19-23; col. 12:28-33 ("Suitable materials include elastomeric polymers or natural rubber (latex). . . . Polymeric stents can be provided with relatively fluid impenetrable walls, or porous walls such as to allow drug delivery, as will be apparent to one of skill in the art."); col. 12:63-65 ("Suitable coating materials include elastic materials such as polyethylene or PET or other materials that can be readily selected by one of skill in the art."); col. 18:51-19:9; col. 19:18-30; col. 19:31-32; col. 19:61-63; col. 20:33-49; col. 20:51-57.

Palmaz '417: Col. 6:66-68; col. 11:3-14 ("Examples of a suitable biologically compatible coating would be porous polyurethane, Teflon™ or other conventional biologically inert plastic materials."); col. 11:26-31 ("Examples of biologically compatible coatings would include coatings made of absorbable polymers such as those used to manufacture absorbable sutures. Such absorbable polymers include polyglycoides, polyacoides, and copolymers thereof.").

Tice '330: Col. 3:20-33 ("Suitable wall forming materials include polystyrene, ethylcellulose, cellulose acetate, hydroxyl propylmethylcellulose phthalate, cellulose acetate, dibutylaminohydroxypropyl ether, polyvinylbutyral, polyvinyl formal, poly(meth)acrylic acid ester, polyvinylacetal-diethylamino acetate, 2-methyl-5-vinyl pyridine methacrylate-methacrylic acid copolymer, polycarbonate, polyesters, polypropylene, vinylchloride-vinylacetate copolymer, polysaccharides, glycerol distearate, and the like. A preferred group of polymeric wall forming materials includes those which are biodegradable such as aliphatic polyesters including polylactide, polyglycolide, polycaprolactone and copolymers thereof."); col. 8:38-51.

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); col. 3:7-18; col. 3:56-63; col. 4:31-34 ("The outer membrane surface is nonporous, while porous inner membrane surface allows for the diffusion therethrough of active factor 26."); col. 5:18-28 ("In a preferred embodiment of the invention, the outer surface of the membrane is impermeable to solutes of any size, while the inner membrane surface contains pores [that] enable the active factors to diffuse out of the membrane and into the lumen of the channel."); col. 6:17-22 ("The layering procedure allows deposition of an impermeable coat on the outer surface of the device, insuring that the active factors incorporated into the membrane walls will be inhibited from diffusing through the external surface, and will diffuse only through the inner membrane surface into the lumen of the channel."); 6:54-61; col. 9:18-10:3.

Folkman '560: col. 2:43-68 ("A biocompatible plastically deformable polymer matrix . . . substantially impermeable to a macromolecule"); col. 3:18-23 ("The polymer matrixes, which are suitably used in the present invention, are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:36-51 ("Typical polymeric material suitable for forming the matrix . . . include . . . alkylene-vinyl acetate copolymers . . . crosslinked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:52-4:26 ("In the presently preferred embodiment the polymeric materials useful for forming the matrix are the ethylene vinyl ester copolymers of the general formula . . ."); col. 11:56-12:20.

Cohen '496: Col. 3:26-45 ("The polymer matrices . . . are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:65-4:39 ("In a presently preferred embodiment, the polymeric materials useful for forming the matrix are the ethylenevinyl ester copolymers of the general formula . . ."); col. 9:40-10:17; col. 10:18-32.

Schiraldi '243: Col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 1:58-60; col. 2:30-51; col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 9:36-55; col. 10:12-18.

Valentini '029: Abstract; col. 2:29-57 ("It has been discovered that the repair of severed or avulsed nerves can be greatly enhanced by the use of selectively permeable polymeric materials as nerve guidance channels. . . . The devices can be formed from various polymeric materials, such as acrylic copolymers, polyvinylidene fluoride or polyurethane isocyanate Preferable, the materials allow passage therethrough of solutes having a molecular weight of about 100,000 daltons or less. . . . The nerve guidance channels of the present invention are also preferably designed to retain nerve growth factors secreted at the anastomatic site or seeded therein, as well as retain any luminal matrix material placed inside the guidance channels.").

Greco '135: Col. 3:48-4:1 ("These devices will consist of organic polymers and/or metallic materials including: . . . polyethylene . . . elastomeric organosilicon polymers, such as polysiloxanes, e.g. Silastic ®").

Aebischer '627: Col. 3:57-4:3 ("The polymeric insert includes pores having a molecular weight exclusion of from about 1 kD to about 1,000 kD, but preferably from about 25kD to about 100 kD."); col. 4:11-27 ("The terms 'semipermeable' is used herein to describe biocompatible membranes that allow the diffusion therethrough of molecules having a relatively low molecular weight, while excluding the passage of those having a relatively high molecular weight. . . . The semipermeable membrane can me made of various polymeric compositions such as polyvinylchloride, polyacrylonitrile, polyvinylidene fluoride, polysteyrene, polymethylmethacrylate, polysulfone, and acrylic copolymers."); col. 7:57-8:14 ("In this

embodiment, a semi-permeable membrane functions as a protective cell culture device for the neurotransmitter-secreting cells. The pores of the membrane should be large enough to enable the exchange of metabolites with body fluids, and to permit the diffusion therethrough of neurotransmitter produced by the cells therein, but are small enough to bar the passage therethrough of larger elements deleterious to the cells."); col. 13:31-48; col. 13:66-68; col. 14:1-2; col. 14:22-28; col. 14:54-56.

Wood '066: Abstract ("A controlled-release bandage containing therapeutic agents in a poly(vinyl alcohol) cryogel is disclosed. The bandage may include . . . hydrophobic particles to further insure controlled and constant release of therapeutic agents."); col. 2:56-66; col. 23:4-11.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:63-2:2; col. 2:12-15 ("The present invention on the other hand exploits a wrapping material that plastically deforms as it expands . . ."); col. 2:21-38; col. 2:59-64; col. 3:7-16; col. 3:27-33 ("The lining can to advantage be made of polymers or compounds thereof."); col. 3:51-62; col. 3:51-62; col. 5:49-54 ("The thread itself in an endoprosthesis of the type illustrated in Fig. 3 can also be wrapped in a coat of medicated and biodegradable wrapping material. . . . The prosthesis can of course alternatively be enclosed in a flexible-tubular coat."); col. 6:50-55; col. 6:59-62; col. 7:16-35; col. 8:4-8; col. 8:19-10:19.

Lambert '246: Abstract ("Thus, a polyurethane coating is applied to a prosthetic article, the coating then swelled . . . so that substantial quantities of biologically active compounds can be incorporated within the interstices of the polymer."); col. 2:15-34; col. 2:40-49; col. 2:53-65; col. 3:55-4:35 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility to as to enable the application of a stable coating onto substrate (i.e. the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected)."); col. 10:45-67; col. 11:34-59; col. 12:15-41.

Bellamkonda '029: Abstract; col. 10:28-40; 12:13-16 ("Preferably the permselective membrane is fabricated to be impermeable to some of these substances so that they are retained in the proximity of the regenerating nerve ends.").

Dayton '382: Abstract ("The device comprises a stent which is formed from metal or polymers into a predetermined shape which includes a plurality of holes . . . to provide a desired bending modulus. The stent is then coated with a polymer . . . which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids, with the equilibrium being controlled by charge distribution, concentration and molecular weight of the bioactive substance in relation to the pore size of the polymeric carrier for controlled prolonged release of said bioactive substance."); col. 3:62-4:4:17 ("Among these polymers are polymers having a microporous structure, such as . . . biodegradable polylactic acid polymers, polyglycolic acid polymers . . ."); col. 4:24-33 ("A bioactive substance is preferably admixed in the polymer for elution from the microporous structure of the stent or coating on the stent after implantation.

The rate of elution of the bioactive substance is controlled by selecting a pore size for microporous structure . . ."); col. 4: 42-50; col. 4:54-5:3; col. 6:64-7:7 ("The polymer should have a microporous structure with a predetermined pore size."); col. 8:19-33; col. 8:42-59; col. 8:66-9:5; col. 10:1-2.

Burt '036: p. 4:19-33 ("Similarly a wide variety of polymeric carriers may be utilized, representative examples of which include poly(ethylene-vinyl acetate) . . . and copolymers of polylactic acid and polycaprolactone."); p.10:17-25; p.14:9-27 ("As noted above, anti-angiogenic compositions of the present invention comprise an anti-angiogenic factor and a polymeric carrier. In addition to the wide array of anti-angiogenic factors and other compounds discussed above, anti-angiogenic compositions of the present invention may include a wide variety of polymeric carriers, including for example both biodegradable and non-biodegradable compositions."); p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size."); p.51:1-52:35.

Goldin '568: Col. 1:43-62 ("Release by controlled diffusion may be accomplished by means of containment of the therapeutic agent within a substrate whose small pore size and/or tortuosity of diffusion path thereof limits the diffusion of said agent through the substrate. . . . The therapeutic agent can be incorporated within the diffusion-limiting substrate Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:24-29 ("Microporous membranes for release of proteins by controlled diffusion have been fabricated from ethylene vinyl acetate (EVA), and said membranes have been used in vivo in a manner which demonstrates their therapeutic potential."); col. 5:28-34 (" . . . underlayment material of controlled pore size can be created and used to fabricate a device of optimal porosity . . . and accessibility of the releasable macromolecule to biological material at or beyond the membrane's external surface . . ."); Fig. 1A; col. 11:58-12:14; col. 13:53-65; col. 14:1-28; col. 14:66-15:67; col. 31:57-32:7 ("The device of claim 1 wherein said microporous underlayment comprises a polymer."); col. 32:16-22.

Palmaz '665: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3:47-51 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5: 30-32 ("FIGS. 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon."); Figures 5 and 6.

Palmaz '762: Col. 10:28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials."); col.3:65-4:2 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 9:20-25; col. 10:28-43 ("...and the tubular members 71 of grafts, or

prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '337: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3:52-56 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5: 19-21; Figures 5 and 6; col. 8: 28-32; col. 9: 24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Aebischer: p. 283 (disclosing impermeable polymer layer that restricts passage of treating material).

Dev: p. 273 ("We used a commercially available biomedical grade polyurethane Tecoflex is a biocompatible, flexible, and an elastic membrane-forming polymer.").

Claim 6 [6A]: The device of claim 1 whereby the layer is capable of being affixed to a fixation device.

Where Found in the Prior References:

Schwartz '823: Abstract ("A radially expandable stent for implantation within a body lumen having a generally cylindrical body with open proximal and distal ends, the cylindrical body comprising a plurality of metal elements joined to allow flexing of the cylindrical body along the longitudinal axis of the body whereby the stent can conform to a curved body lumen and a polymeric film extending between the metal elements of the stent. The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen."); col. 2:49-53 ("The polymeric film is flexible and preferably an elastic or stretchable film that is capable of conforming to the movement of the metallic stent elements when expanded into contact with a body lumen."); col. 3:58-61 ("The improvement of the present invention includes applying to the above-mentioned type of stent a flexible or elastomeric polymeric film which extends between the metal elements."); col. 4:20-24 ("The term 'film' or 'flexible film' herein therefore means that, as applied to the metal stent elements in a thin cross section, the film is capable of flexing or stretching to preserve the radial expandability and axial flexibility of the implanted stent."); col. 5:59-6:2; col. 6:17-38; col. 6:40-43; col. 6:59-62 ("The flexible film can be applied as a sheath to the metal stent elements after which the stent can be compressed, attached to a catheter, and delivered through a body lumen to a desired location."); col. 8:27-32.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); Fig. 3; col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-33; col. 6:37-45 ("The invention also provides a kit comprising the sheath and a stent. Also disclosed is a device comprising a stent encompassed by the sheath. The initial prototype is a sleeve of polymer, either degradable or non-degradable, that covers the entire stent (Fig. 3). Modifications of the polymer coating include a ring that encompasses the proximal portion of the stent, single or multiple strips that cover a portion of the stent, or a polymer coating with perforations."); col. 6:49-59 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject. Finally, the invention provides a method of inhibiting vascular cell growth in a subject comprising inserting a stent encompassed by a sheath containing an inhibitor of vascular cell growth into a vessel of the subject."); col. 8:58-60; col. 10:24-33 ("In combination, a hollow tubular stent having a predetermined length and a separate sheath removably encompassing at least a portion of said hollow tubular stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug."); col. 12:9-12; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow Controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Col. 1:7-10 ("This invention relates generally to expandable intraliminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement

and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 2:3-55; col. 3:30-32; col. 3:36-39 ("Fig. 9 is a plan view of a sheet of polymeric material in another alternative embodiment including elastic strips for securing the polymeric material wrapped around a stent structural member;"); col. 3:40-41; col. 3:51-54 ("Fig. 14 is a plan view of a sheet of polymeric material in a further alternative embodiment including attachment tabs for securing the polymeric material to a stent structural member;"); Fig. 15; col. 3:55-57 ("Fig. 15 is an elevational view of a drug loaded stent wrapped with the sheet of polymeric material of Fig. 14 and mounted on a balloon dilation catheter for delivery."); Fig. 16; col. 3:58-60 ("Fig. 16 is an enlarged partial sectional view of the drug loaded stent of Fig. 15 showing the sheet of polymeric material wrapped around a slotted tube stent structural member."); col. 4:15-24; col. 4:25-46 ("The planar sheet of polymeric material is preferably adapted to uncoil and expand to match the expansion of the stent structural member. . . . The stent can be mounted on a balloon dilatation catheter, for deployment of the stent in the vasculature of the patient."); col. 4:47-5:3; col. 5:4-9; col. 5:15-17; col. 5:18-25; col. 5:25-31; col. 5:36-48 ("A representative stent structural member with which a sheet of polymeric material can be combined according to the principles of the invention is illustrated in Fig. 8."); col. 6:26-65 ("In another currently preferred embodiment illustrated in Figs. 9-13, the stent that can be drug loaded comprises a stent metal structural member, such as the stent structural member illustrated for example in Fig. 8, and a planar sheet or film of polymeric material, preferably including a plurality of apertures, as will be further explained below."); col. 7:42-53; col. 7:56-62 ("The elastic material attached over the coil of polymeric material helps keep the coil of drug loaded material snug on the stent structural member before it is expanded, and guides its linear expansion during inflation of a balloon dilatation catheter used for deployment of the stent and polymeric drug loaded material in the vasculature or other body lumen of a patient."); col. 8:1-57; col. 9:12-18; col. 9:19-22; col. 10:12-30.

Wolff '208: Col. 2:12-16 ("In all cases, the prostheses of the invention require the presence of an elutable drug compounded to the prosthesis itself. With conventional metal stents, the invention requires a drug-carrying coating overlying at least a portion of the metal."); col. 6:56-58 ("The stent shown in Figs. 2 and 4 is a metallic malleable design which may be forced against a lumen wall by a balloon catheter which fixes it into position."); col. 6:59-62 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously."); col. 9:39-42 ("The device is fixed into place either by radial expansion in devices such as shown in Fig. 1 or are deformed by a balloon catheter in the case of devices in accordance with Fig. 2."); col. 9:60-10:3 ("In yet another embodiment of the invention, a purely polymeric prosthesis such as that having the configuration shown in Fig. 1 can be combined with an expandable metal stent to provide additional support for the prosthesis. . . . By including a metal stent within the lumen of the polymeric prosthesis, the polymeric prosthesis is effectively held against the wall of the body lumen by the strength of the metal stent."); col. 10:3-45 ("The stents are arranged on the distal end of the catheter such that the catheter can provide remote, transluminal deployment of the stents, with the metal stent inside

the polymeric stent, from an entry point into a selected portion of the body lumen to be treated and also remote actuation of an expansion mechanism from the proximal end of the catheter. The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen."); col. 10:46-59; col. 10:59-11:20; col. 11:50-53.

Berg '354: Page 2:3-4 ("This invention relates to intravascular stents for treatment of injuries to blood vessels and particularly to stents having a framework onto which a therapeutic substance or drug is applied."); p. 2:43-53 ("Viewed from a further aspect the invention provides the use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug-eluting surface coating."); p.2:55-3:7; p. 3:31-34; p.3:54-55 ("The solution is applied to the stent and the solvent is allowed to evaporate, thereby leaving on the stent surface a coating of the polymer and the therapeutic substance."); p. 6:6-11; p. 6:17-19; p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Ding '536: Col. 1:24-32 ("The present invention relates generally to providing biostable elastomeric coatings on the surfaces of implants which incorporate biologically active species having controlled release characteristics in the coating particularly to provide a non-thrombogenic surface during and after timed release of the biologically active species. The invention is particularly described in terms of coating on therapeutic expandable stent prostheses for implantation in body humans, e.g., vascular implantation."); col. 3:19-27 ("Accordingly, it is primary object of the present invention to provide a coating and process for coating a stent to be used as a deployed stent prostheses, the coating being capable of effective controlled long-term delivery of biologically active materials."); col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 12:20-23 ("It will be appreciated that the mechanism of incorporation of the biologically active species into a thin surface coating structure applicable to a metal stent is an important aspect of the present invention."); col 13:13-26 ("A medical device having at least a portion which is implantable into the body of a patient, wherein at least a part of the device portion is metallic and at least part of the metallic device portion is covered with a coating for release of at least one biologically active material . . .").

Dinh '227: Col. 3:41-46 ("Fig. 1 is an elevational view of a balloon catheter with a metallic stent including a fibrin coating according to the present invention. . . ."); Fig. 1; Fig. 2; col. 3:64-65; Fig. 10; col. 5:3-7; col. 6:56-67 ("The inclusion of a polymer in intimate contact with a drug on the underlying stent structure allows the drug to be retained on the stent in a resilient matrix during expansion of the stent and also slows the administration of drug following implantation."); col. 7:10-21; col. 7:56-64 ("In another embodiment of the invention, the coating

of polymer and drug on the stent is achieved by forming a first fibrin layer on the stent body which incorporates the therapeutic substance and then applying a second layer of fibrin."); col. 8:26-43 ("The stent can also have underlying polymeric or metallic structural elements onto which the fibrin is applied or the stent can be a composite of fibrin intermixed with a polymer."); col. 8:49-60; col. 9:49-50 ("The resulting fibrin stent includes the stent embedded in a very thin elastic film of fibrin."); col. 9:59-63; col. 10:29-31 ("The metal stent portion mentioned above may be eliminated to make a fibrin tube which can be placed on a balloon catheter and expanded into place in a body lumen."); col. 11:60-62 ("It will be readily appreciated that a fibrin stent with an attached metallic framework can be readily provided by this molding method."); col. 12:24-28.

Domb '055: Abstract ("Preferred polymeric coatings are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); col. 1:12-15 ("This invention relates to invasive medical devices for delayed/sustained release of pharmaceutical compositions from a polymer that is coated or incorporated into the devices."); col. 4:33-36; col. 5:24-27 ("Devices are provided having a polymer coating incorporating compounds inhibiting inflammation and infection, along with subsequent tissue growth onto and around the device."); col. 5:35-38; col. 5:46-48; col. 5:60-6:1; col. 6:3-7; col. 7:10-20; col. 7:40-52; col. 9:15-30; col. 9:55-10:2; col. 10:21-52; col. 10:60-11:11; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Col. 1:33-36 ("In addition, antimicrobial compositions useful as coatings for medical devices or for forming the device itself are disclosed . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 2:48-65; Col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages."); col. 16:16-23 ("The catheter was dipped in the coating vehicle while the vehicle was being continuously agitated to insure a uniform suspension. The coated catheter was the dried. A tightly adherent coating on the catheter was thus provided."); col. 19:11-16; col. 22:31-37; col. 30:49-53; col. 36:65-37:7.

Hunter '981: Col. 1:12-17 ("The present invention relates generally to compositions and methods for treating cancer and other angiogenic-dependent diseases, and more specifically, to compositions comprising anti-angiogenic factors and polymeric carriers, stents which have been coated with such compositions, as well as method for utilizing these stents and compositions."); col. 4:20-23; col. 4:38-41; col. 5:14-16; col. 5:17-22; col. 5:28-32; col. 22:3-6 ("As noted above, the present invention also provides stents, comprising a generally tubular structure . . . the surface of which is coated with a composition as described above."); col. 22:23-39 ("Representative examples of stents include those described in . . ."); col. 22:40-64 ("Stents may be coated with anti-angiogenic compositions or anti-angiogenic factors of the present invention in a variety of manners, including for example: (a) by directly affixing to the stent an anti-angiogenic composition (e.g., by either spraying the stent with a polymer/drug film, or by dipping the stent into a polymer/drug solution) . . . (d) by inserting the stent into a sleeve of mesh which is comprised of or coated with an anti-angiogenic composition . . ."); col. 23:6-12; col. 23:46-51; col. 24:45-51; col. 24:66-25:5; col. 25:24-29; col. 25:48-54; col. 26:24-29; col. 69:22-26 ("In this study, strecker stents were coated with an EVA polymer containing paclitaxel at concentration of 33%, 10%, and 2.5% and were tested for their ability to inhibit angiogenesis on the CAM."); 86:56-59; col. 87:11-22; col. 88:19-26.

Kowligi '782: Abstract ("A non-porous coated PTFE graft includes a PTFE tube having a conventional porous inner cylindrical wall and a non-porous elastomeric coating applied over at least a portion of the outer cylindrical wall of the PTFE tube to render such portion of the outer cylindrical wall non-porous."); col. 2:38-47; col. 2:53-67; col. 3:7-12; col. 3:27-37; Col. 2:60-67 ("PTFE tube 32 includes an inner cylindrical wall and an opposing outer cylindrical wall. As shown in Fig. 2, outer cylindrical wall 36 is coated entirely around its circumference by a uniformly thick coating of a biocompatible elastomer."); col. 5:4-7; col. 5:16-21.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 3:49-53; col. 5:57-61; col. 7:55-58; col. 11:52-56 ("The method in accordance with claim 1, wherein the substrate is selected from the group consisting of a metallic stent, a heart valve, a metallic prosthesis, a prosthetic joint, a pacemaker, a catheter, a balloon coating, an ocular implant and a contact lens").

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p. 10:17-21; p. 13:20-24; claim 8 ("The method according to claim 1, wherein the substrate is selected from a metallic stent, a heart valve, a metallic prosthesis, a prosthetic joint, a pacemaker, a catheter, a balloon coating, an ocular implant or a contact lens").

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8; p. 2:29-30; p. 3:11-13.

Myler '563: Col. 2:13-15; col. 4:30-43 ("In a preferred embodiment, the interior and exterior walls of stent 10 are enclosed in a thin polymeric envelop."); col. 4:44-52 ("The envelope may be produced, for example, by inserting the stent into a preformed tubular envelope having one open end and sealing the envelope closed, or other techniques within the skill in the art."); col. 5:1-16; col. 5:50-54; col. 12:63-13:1; col. 13:5-14.

Palmaz '417: Col. 11:3-8 ("With reference now to Figs. 5 and 6, prostheses, or grafts of the type previously described in connection with Figs. 1A and 1B are shown, and the tubular members of grafts, or prostheses, have a biologically inert or biologically compatible coating placed upon wall surfaces of tubular shaped members."); col. 13:51-53 ("The method of claim 1, wherein at least one prosthesis is provided with a biologically compatible coating on the outer surface of the prosthesis.").

Wood '066: Col. 7:51-65 ("The PVA cryogel bandage may be supported by a woven or non-woven fabric of film support."); col. 23:15-23.

Strecker '746: Abstract; col. 1:63-2:2; col. 2:12-15 ("The present invention on the other hand exploits a wrapping material that plastically deforms as it expands and accordingly exerts no restoration force on the stent, ensuring persistent expansion."); col. 2:21-32 ("This embodiment has a wrinkled lining around the as yet unexpanded stent."); col. 2:33-38; col. 2:47-53; col. 2:59-64; col. 2:65-3:4 ("[T]he lining can be a flexible tubular membrane or sleeve wrapped around the prosthesis and secured."); col. 6:30-64; col. 7:16-35; col. 8:4-9; col. 8:19-10:19; Figs. 7 & 8.

Lambert '246: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 2:15-34; col. 2:53-65; col. 3:50-54; col. 10:51-54; col. 11:41-44; col. 12:23-26.

Dayton '382: Col. 4:4-10; col. 5:50-60; col. 8:64-65.

Burt '036: p.21:25-22:6 ("Stents may be coated with anti-angiogenic compositions or anti-angiogenic factors of the present invention using a variety of methods . . .").

Palmaz '665: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3: 55-65 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter..."); col.3:47-51 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway.").

Palmaz '762: Col.3:65-4:2 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 10: 28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '337: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3: 52-56 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5: 19-21; Figures 5 and 6; col. 9: 24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Dev: p.273-74 (disclosing mounting stent on balloon catheter for delivery).

Claim 7 [7A]: The device of claim 4 whereby the formed chamber is capable of containing the at least one treating material adjacent to a damaged tissue.

Where Found in the Prior References:

Schwartz '823: Abstract; col. 2:29-40; col. 2:49-53; col. 3:58-61 ("The improvement of the present invention includes applying to the above-mentioned type of stent a flexible or elastomeric polymeric film which extends between the metal elements."); col. 3:64-4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof."); col. 6:17-20; col. 7:25-8:11.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); Fig. 3; col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen

into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-33; col. 5:34-6:29; col. 6:37-41; col. 6:41-45 ("Modifications of the polymer coating include a ring that encompasses the proximal portion of the stent, single or multiple strips that cover a portion of the stent, or a polymer coating with perforations."); col. 8:23-25 ("Ethylene vinyl acetate copolymer (EVA) (Catalog #34,691-8) was obtained from Aldrich Chemical Company, Inc. (Milwaukee, Wis.); col. 10:24-33; col. 12:1-6; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow Controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Col. 1:7-10 ("This invention relates generally to expandable intraliminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 1:64-2:2 ("The polymer material can be a thermoplastic or an elastomer, for example, so that the film can stretch or deform radially when the stent structural member is expanded. The film of polymer material can be formed as a solid sheet, or can incorporate holes of various sizes and shapes to promote rapid endothelialization."); col. 4:15-24; col. 4:25-46; col. 4:47-5:3; col. 5:4-9; col. 5:49- 6:25 ("The polymeric material is preferably selected from thermoplastic and elastomeric polymers. . . . In another currently preferred embodiment, the polymeric material can be ethylene vinyl acetate (EVA) . . ."); col. 6:26-65; col. 7:23-42; col. 7:63-65; col. 8:12-57; col. 9:5-12; col. 10:12-30.

Wolff '208: Col. 2:7-16 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:28-30 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 6:59-62 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously. The polymer may be biostable or bioabsorbable. If biostable, the drug would diffuse out of the polymer."); col. 6:64-67; col. 7:59-61; col. 9:23-33 ("That layer may be a simple barrier which

limits diffusion of drugs in the polymer. In that event, the smaller molecules could elute out immediately, while larger compounds would not elute until later when the layer has biodegraded."); col. 12:37-40 ("8. The device of claim 1 also comprising a barrier coating of polymeric material on the drug-containing filament to limit the rate of drug elution.").

Berg '354: Page 2:43-54 ("Viewed from a further aspect the invention provides the use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug-eluting surface coating."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:29-31 ("Also, stents made with biostable or bioabsorbable polymers such as poly(ethylene terephthalate), polyacetal, poly(lactic acid), poly(ethylene oxide)/poly(butylene terephthalate) copolymer could be used in the present invention. "); Table 1; p. 4:5-24; p. 6:6-11; p. 6:15; p. 6:24-35; p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Abstract ("A stent made of biodegradable material includes a drug that is released at a rate controlled by the rate of degradation of the biodegradable material."); col. 2:16-17; col. 4:1-5 ("In one embodiment, the main body includes a film that is preferable combined with the plurality of fibers disposed around the main body. The film combined with the plurality of fibers defines the outer surface of the main body."); col. 4:15-16 ("Preferable, the main body of the stent includes a film covering the inner surface."); col. 4:19-22.

Ding '536: Abstract ("The coating includes a relatively thin layer of biostable elastomeric material containing an amount of biologically active material, particularly heparin, dispersed in the coating in combination with a non-thrombogenic surface."); col. 1:24-29 ("The present invention relates generally to providing biostable elastomeric coatings on the surfaces of implants which incorporate biologically active species having controlled release characteristics in the coating particularly to providing a non-thrombogenic surface during and after timed release of the biologically active species."); col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 5:10-56 ("Polymers generally suitable for the undercoats or underlayers include silicones (e.g., polysiloxanes and substituted polysiloxanes), polyurethanes, thermoplastic elastomers in general, ethylene vinyl acetate copolymers, polyolefin elastomers, polyamide elastomers, and EPDM rubbers. The above-referenced materials are considered hydrophobic with respect to the contemplated environment of the invention."); col. 12:62-13:2; col. 13:13-26; col. 13:37-40; col. 14:5-17; col. 14:22-34.

Dinh '227: Col. 2:51-54 ("To accomplish this while not affecting the strength of the overall fibrin stent structure, a first layer is applied to a stent body, the first layer incorporating a

polymer and the therapeutic substance."); col. 2:62-66 ("The inclusion of a polymer in intimate contact with a drug on the underlying stent structure allows the drug to be retained on the stent in a resilient matrix during expansion of the stent and also slows the administration of drug following implantation."); col. 3:10-14; col. 3:25-38; col. 5:3-7; col. 5:44-55; col. 5:56-57; col. 6:13-19 ("In U.S. Pat. No. 4,548,736 issued to Muller et al., a dense fibrin composition is disclosed which can be a bioabsorbable matrix for delivery of drugs to a patent. Such a fibrin composition can also be used in the present invention by incorporating a drug or other therapeutic substance useful in diagnosis or treatment of body lumens to the fibrin provided on the stent."); 6:50-56 ("Alternatively . . . a dense fibrin composition suitable for drug delivery can be made without the use of microcapsules by adding the drug directly to the fibrin followed by compression of the fibrin into a sufficiently dense matrix that a desired elution rate for the drug is achieved."); col. 6:62-67; col. 7:10-13; col. 7:56-64 ("In another embodiment of the invention, the coating of polymer and drug on the stent is achieved by forming a first fibrin layer on the stent body which incorporates the therapeutic substance and then applying a second layer of fibrin."); col. 8:52-60 ("Fig. 2 shows an alternative stent in which a fibrin film has been affixed to the underlying metallic framework by affixing it to the stent . . ."); col. 8:64-9:3; col. 12:24-28; col. 12:38-50.

Domb '055: Abstract ("Devices are provided having a polymer coating incorporating compounds inhibiting inflammation and infection, along with subsequent tissue growth onto and around the device. . . . Preferred polymeric coating are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); col. 1:12-15 ("This invention relates to invasive medical devices for delayed/sustained release of pharmaceutical compositions from a polymer that is coated or incorporated into the devices."); col. 3:54-57 ("In the preferred embodiments, these have utilized bioerodible polymers as the matrix for the drug to be released, usually as a function of diffusion and erosion of the polymer."); col. 4:22-36; col. 5:24-37; col. 5:41-45; col. 5:48-6:1; col. 6:24-26 ("Examples of suitable polymers include ethylene vinyl acetate, polyurethane, silicones, hydrogels, polyurethane, and polyvinyl chloride."); col. 7:10-20; col. 7:40-52; col. 9:15-30; col. 9:55-10:2; col. 10:21-52; col. 10:60-11:11; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 11:36-38 ("The medical device of claim 1, wherein the polymer is selected from the group consisting of polyurethane, ethylene vinyl acetate, silicones, hydrogels, and polyvinyl chloride."); col. 11:39-44; col. 12:11-22; col. 12:23-25; col. 12:26-31; col. 12:32-42.

Fox '096: Abstract ("A method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers, and antimicrobial agents . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group

consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 2:48-65; col. 3:55-67 ("The polymeric coating agent component of the coating vehicle of the present invention is selected from the group consisting of biomedical polyurethanes, biomedical silicones, biodegradable polymers and combinations thereof."); col. 19:11-16; col. 31:62-64.

Hunter '981: Col. 1:12-17; col. 3:42-45 ("Within one aspect of the present invention, compositions are provided (anti-angiogenic compositions) comprising (a) an anti-angiogenic factor and (b) a polymeric carrier."); col. 3:53-61; col. 12:23-25 ("As noted above, the present invention provides compositions comprising an anti-angiogenic factor, and a polymeric carrier."); col. 16:31-56; col. 17:63-18:7 ("[T]he anti-angiogenic compositions of the present invention may be formed as a film. . . . Such films are preferably flexible with a good tensile strength . . . and has controlled permeability."); col. 22:3-7; col. 22:54-58; col. 47:58-49:7; col. 52:4-8; col. 69:19-62; col. 84:62-86:24; 86:56-59; col. 87:11-22; col. 88:19-26.

Kowligi '782: Abstract ("The elastomeric coating is made of polyurethane or another biocompatible non-porous elastomers and precludes tissue ingrowth into the outer cylindrical wall, minimizes suture hold bleeding, and increases suture retention strength, while reducing the incidence of serous weepage."); col. 1:18-26; col. 2:15-20; col. 2:38-47; col. 2:53-59; col. 3:27-37; Fig. 1; Fig. 2; Fig. 3; col. 2:60-67 ("PTFE tube 32 includes an inner cylindrical wall and an opposing outer cylindrical wall. As shown in Fig. 2, outer cylindrical wall 36 is coated entirely around its circumference by a uniformly thick coating of a biocompatible elastomer."); col. 3:27-38; col. 4:16-27 ("In regard to elastomeric coating 38 shown in Fig. 2, such elastomeric coating is selected to be a biocompatible elastomers and may be selected from the group consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 4:37-39 ("The elastomeric coating should also be sufficiently non-porous to preclude serous weepage and inhibit tissue ingrowth therethrough."); col. 5:4-7; col. 7:49-8:9; col. 8:38-44; col. 9:65-10:6; col. 10:18-24; col. 10:33-42; col. 10:43-50; col. 10:51-59; col. 10:60-67.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 2:16-35; col. 2:40-50; col. 3:8-12; col. 3:29-32; col. 3:33-49; col. 3:55-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); col. 7:29-32; col. 7:38-41; col. 10:57-64; col. 11:49-51; col. 11:65-12:13; col. 12:43-64; col. 13:13-19.

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated

within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p. 3:10-31 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); p. 4:2-12; p. 6:21-28 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); claim 1:1-14; claim 8:1-5; claim 10:1-3; claim 11:1-13; claim 22; claim 23:1-14; claim 19:4-31.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8.

Myler '563: Col. 2:10-13; col. 3:13-15; col. 3:52-54; col. 4:30-43 ("In a preferred embodiment, the interior and exterior walls of stent 10 are enclosed in a thin polymeric envelope. . . . Suitable envelope materials include elastic materials such as latex and others that can be readily selected by one of skill in the art."); col. 5:1-16; col. 5:39-41 ("For the above reasons, even the expanded pores for drug delivery should be small enough to maximize or prevent cell penetration, but large enough for drug delivery."); col. 12:11-13; col. 12:19-23; col. 12:28-33 ("Suitable materials include elastomeric polymers or natural rubber (latex). . . . Polymeric stents can be provided with relatively fluid impenetrable walls, or porous walls such as to allow drug delivery, as will be apparent to one of skill in the art."); col. 12:63-65 ("Suitable coating materials include elastic materials such as polyethylene or PET or other materials that can be readily selected by one of skill in the art."); col. 18:51-19:9; col. 19:18-30; col. 19:31-32; col. 19:61-63; col. 20:33-49; col. 20:51-57.

Palmaz '417: Col. 6:66-68; col. 11:3-14 ("Examples of a suitable biologically compatible coating would be porous polyurethane, Teflon™ or other conventional biologically inert plastic materials."); col. 11:26-31 ("Examples of biologically compatible coatings would include coatings made of absorbable polymers such as those used to manufacture absorbable sutures. Such absorbable polymers include polyglycoides, polyacoides, and copolymers thereof. ").

Tice '330: Col. 3:20-33 ("Suitable wall forming materials include polystyrene, ethylcellulose, cellulose acetate, hydroxyl propylmethylcellulose phthalate, cellulose acetate, dibutylaminohydroxypropyl ether, polyvinylbutyral, polyvinyl formal, poly(meth)acrylic acid ester, polyvinylacetal-diethylamino acetate, 2-methyl-5-vinyl pyridine methacrylate-methacrylic acid copolymer, polycarbonate, polyesters, polypropylene, vinylchloride-vinylacetate copolymer, polysaccharides, glycerol distearate, and the like. A preferred group of polymeric wall forming materials includes those which are biodegradable such as aliphatic polyesters including polylactide, polyglycolide, polycaprolactone and copolymers thereof."); col. 8:38-51.

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the

active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); col. 3:7-18; col. 3:56-63; col. 4:31-34 ("The outer membrane surface is nonporous, while porous inner membrane surface allows for the diffusion therethrough of active factor 26."); col. 5:18-28 ("In a preferred embodiment of the invention, the outer surface of the membrane is impermeable to solutes of any size, while the inner membrane surface contains pores [that] enable the active factors to diffuse out of the membrane and into the lumen of the channel."); col. 6:17-22 ("The layering procedure allows deposition of an impermeable coat on the outer surface of the device, insuring that the active factors incorporated into the membrane walls will be inhibited from diffusing through the external surface, and will diffuse only through the inner membrane surface into the lumen of the channel."); 6:54-61; col. 9:18-10:3.

Folkman '560: col. 2:43-68 ("A biocompatible plastically deformable polymer matrix . . . substantially impermeable to a macromolecule"); col. 3:18-23 ("The polymer matrixes, which are suitably used in the present invention, are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:36-51 ("Typical polymeric material suitable for forming the matrix . . . include . . . alkylene-vinyl acetate copolymers . . . crosslinked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:52-4:26 ("In the presently preferred embodiment the polymeric materials useful for forming the matrix are the ethylene vinyl ester copolymers of the general formula . . ."); col. 11:56-12:20.

Cohen '496: Col. 3:26-45 ("The polymer matrices . . . are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:65-4:39 ("In a presently preferred embodiment, the polymeric materials useful for forming the matrix are the ethylenevinyl ester copolymers of the general formula . . ."); col. 9:40-10:17; col. 10:18-32.

Schiraldi '243: Col. 1:8-21 ("The extruded film drug delivery system of the present invention, which has incorporated therein the medicament to be dispensed, is so thin and flexible when wet as to be unobtrusive to the patient after it has been properly positioned and placed in the mouth."); col. 1:58-60; col. 2:30-51; col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 9:36-55; col. 10:12-18.

Valentini '029: Abstract ("Medical devices employing semipermeable materials, such as acrylic copolymers, polyurethane isocyanate, and other biocompatible semipermeable polymers, are disclosed for use as guidance channels in regenerating nerves. . . . The guidance materials

are chosen such that they are capable of allowing the diffusion of nutrients and other metabolites to the regenerating nerve site while excluding fibroblasts and other scar-forming cells."); col. 2:29-57 ("It has been discovered that the repair of severed or avulsed nerves can be greatly enhanced by the use of selectively permeable polymeric materials as nerve guidance channels. . . . The devices can be formed from various polymeric materials, such as acrylic copolymers, polyvinylidene fluoride or polyurethane isocyanate Preferable, the materials allow passage therethrough of solutes having a molecular weight of about 100,000 daltons or less. . . . The nerve guidance channels of the present invention are also preferably designed to retain nerve growth factors secreted at the anastomatic site or seeded therein, as well as retain any luminal matrix material placed inside the guidance channels."); col. 2:58-3:14; col. 4:46-59; col. 5:13-32 ("The success rate and quality of peripheral nerve regeneration was dramatically enhanced through the use of a semipermeable material."); col. 5:42-6:12 ("The permselective characteristics of the inner membrane allow the exchange of nutrients, while concentrating growth factors released by the nerve and excluding scar-forming cells."); col. 6:14-24; col. 6:31-42.

Greco '135: Col. 3:48-4:1 ("These devices will consist of organic polymers and/or metallic materials including: . . . polyethylene . . . elastomeric organosilicon polymers, such as polysiloxanes, e.g. Silastic ®").

Aebischer '627: Col. 3:57-4:3 ("The polymeric insert includes pores having a molecular weight exclusion of from about 1 kD to about 1,000 kD, but preferably from about 25kD to about 100 kD."); col. 4:11-27 ("The terms 'semipermeable' is used herein to describe biocompatible membranes that allow the diffusion therethrough of molecules having a relatively low molecular weight, while excluding the passage of those having a relatively high molecular weight. . . . The semipermeable membrane can be made of various polymeric compositions such as polyvinylchloride, polyacrylonitrile, polyvinylidene fluoride, polystyrene, polymethylmethacrylate, polysulfone, and acrylic copolymers."); col. 7:57-8:14 ("In this embodiment, a semi-permeable membrane functions as a protective cell culture device for the neurotransmitter-secreting cells. The pores of the membrane should be large enough to enable the exchange of metabolites with body fluids, and to permit the diffusion therethrough of neurotransmitter produced by the cells therein, but are small enough to bar the passage therethrough of larger elements deleterious to the cells."); col. 13:31-48; col. 13:66-68; col. 14:1-2; col. 14:22-28; col. 14:54-56.

Wood '066: Abstract ("A controlled-release bandage containing therapeutic agents in a poly(vinyl alcohol) cryogel is disclosed. The bandage may include . . . hydrophobic particles to further insure controlled and constant release of therapeutic agents."); col. 2:56-66; col. 23:4-11.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:63-2:2; col. 2:12-15 ("The present invention on the other hand exploits a wrapping material that plastically deforms as it expands . . ."); col. 2:21-38; col. 2:59-64; col. 3:7-16; col. 3:27-33 ("The lining can to advantage be made of polymers or compounds thereof."); col. 3:51-62; col. 3:51-

62; col. 5:49-54 ("The thread itself in an endoprosthesis of the type illustrated in Fig. 3 can also be wrapped in a coat of medicated and biodegradable wrapping material. . . . The prosthesis can of course alternatively be enclosed in a flexible-tubular coat."); col. 6:50-55; col. 6:59-62; col. 7:16-35; col. 8:4-8; col. 8:19-10:19.

Lambert '246: Abstract ("Thus, a polyurethane coating is applied to a prosthetic article, the coating then swelled . . . so that substantial quantities of biologically active compounds can be incorporated within the interstices of the polymer."); col. 2:15-34; col. 2:40-49; col. 2:53-65; col. 3:55-4:35 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility to as to enable the application of a stable coating onto substrate (i.e. the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected)."); col. 10:45-67; col. 11:34-59; col. 12:15-41.

Bellamkonda '029: Abstract ("A nerve guidance channel for use in regenerating severed nerve is prepared containing a tubular semi-permeable membrane having openings adapted to receive the ends of a severed nerve, and an inner lumen containing the matrix having an adhesive peptide fragment through which the nerve can regenerate."); col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 4:9-14; col. 4:21-39 ("Any suitable hydrogel may be used as the substrate for the bioartificial extracellular matrices of this invention."); col. 4:48-57; col. 5:10-14 ("Several physical properties of the hydrogel matrices of this invention are dependent on gel concentration. Increase in gel concentration may change the gel pore radius, morphology, or its permeability to different molecular weight proteins."); col. 7:13-25; col. 10:28-40 ("Permeable channels with a molecular weight cut-off of 50,000 daltons allowed regeneration of nerves in a mouse sciatic nerve model."); col. 10:41-63; col. 10:64-11:13; col. 12:13-16 ("Preferably the permeable membrane is fabricated to be impermeable to some of these substances so that they are retained in the proximity of the regenerating nerve ends."); col. 12:17-25 ("Briefly, various polymers and polymer blends can be used to manufacture the nerve guidance channel."); col. 12:42-49; col. 19:7-16; col. 23:54-24:55.

Dayton '382: Abstract ("The device comprises a stent which is formed from metal or polymers into a predetermined shape which includes a plurality of holes . . . to provide a desired bending modulus. The stent is then coated with a polymer . . . which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids, with the equilibrium being controlled by charge distribution, concentration and molecular weight of the bioactive substance in relation to the pore size of the polymeric carrier for controlled prolonged release of said bioactive substance."); col. 3:62-4:4:17 ("Among these polymers are polymers having a microporous structure, such as . . . biodegradable polylactic acid polymers, polyglycolic acid polymers . . ."); col. 4:24-33 ("A bioactive substance is preferably admixed in the polymer for elution from the microporous structure of the stent or coating on the stent after implantation. The rate of elution of the bioactive substance is controlled by selecting a pore size for microporous structure . . ."); col. 4: 42-50; col. 4:54-5:3; col. 6:64-7:7 ("The polymer should

have a microporous structure with a predetermined pore size."); col. 8:19-33; col. 8:42-59; col. 8:66-9:5; col. 10:1-2.

Burt '036: p. 4:19-33 ("Similarly a wide variety of polymeric carriers may be utilized, representative examples of which include poly(ethylene-vinyl acetate) . . . and copolymers of polylactic acid and polycaprolactone."); p.10:17-25; p.14:9-27 ("As noted above, anti-angiogenic compositions of the present invention comprise an anti-angiogenic factor and a polymeric carrier. In addition to the wide array of anti-angiogenic factors and other compounds discussed above, anti-angiogenic compositions of the present invention may include a wide variety of polymeric carriers, including for example both biodegradable and non-biodegradable compositions."); p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size."); p.51:1-52:35.

Goldin '568: Col. 1:43-62 ("Release by controlled diffusion may be accomplished by means of containment of the therapeutic agent within a substrate whose small pore size and/or tortuosity of diffusion path thereof limits the diffusion of said agent through the substrate. . . . The therapeutic agent can be incorporated within the diffusion-limiting substrate Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:24-29 ("Microporous membranes for release of proteins by controlled diffusion have been fabricated from ethylene vinyl acetate (EVA), and said membranes have been used in vivo in a manner which demonstrates their therapeutic potential."); col. 5:28-34 (" . . . underlayment material of controlled pore size can be created and used to fabricate a device of optimal porosity . . . and accessibility of the releasable macromolecule to biological material at or beyond the membrane's external surface . . ."); Fig. 1A; col. 11:58-12:14; col. 13:53-65; col. 14:1-28; col. 14:66-15:67; col. 31:57-32:7 ("The device of claim 1 wherein said microporous underlayment comprises a polymer."); col. 32:16-22.

Palmaz '665: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3:47-51 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5: 30-32 ("FIGS. 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon."); Figures 5 and 6.

Palmaz '337: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3:52-56 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5: 19-21; Figures 5 and 6; col. 8: 28-32; col. 9: 24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '762: Col. 10:28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials."); col.3:65-4:2 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 9: 20-25; col. 10: 28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Zaffaroni '254: Abstract ("The wall is formed in at least a part of a microporous material..."); col. 1: 19-23 ("The wall of the device is comprised in at least a part of a microporous material..."); col. 3: 5-10; col. 3: 48-53; col. 4: 47-54 ("Wall 11 is formed of a microporous material the micropores 15 of which contain a drug release rate controlling medium, not shown, permeable to the passage of drug, as by diffusion, or by convection,, or by a concurrent operation of both, but the rate of passage of the drug through the medium in the micropores is lower than the rate of passage of drug through the solid drug carrier."); col. 5: 3-11.

Aebischer: p. 283 (disclosing impermeable polymer layer that restricts passage of treating material).

Dev: p. 273 ("We used a commercially available biomedical grade polyurethane Tecoflex is a biocompatible, flexible, and an elastic membrane-forming polymer.").

Claim 8 [8A]: A method of treating a damaged tissue to promote repair comprising:

Where Found in the Prior References

Peterson '166: Abstract ("The composition of the system is particularly effective for delivering medication systemically to a host animal over a prolonged period of time after being surgically implanted or injected subcutaneously."); col. 2:3-5 ("The delivery system is usually implanted subcutaneously by injection or incision in an animal, including the human body."); col. 2:24-27 ("The time-release chemical delivery systems of this invention are intended for implantation, either surgically or by injection in animals, including humans."); col. 11:23-24 ("A time release chemical delivery system for implantation in animal host comprising . . .").

Schwartz '823: Abstract ("The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen. The stent is especially useful for repairing an injury to blood

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vessels caused during angioplasty procedures."); col. 2:16-24 ("It is therefore an object of the present invention to provide a stent having longitudinal flexibility which allows it to conform to curves and variations in body lumens. . . . It is also an object of the present invention to provide a stent capable of delivering therapeutic agents to a blood vessel."); col. 2:29-37 ("In a radially expandable stent for implantation within a body lumen, the stent having a generally cylindrical body with open proximal and distal ends, the cylindrical body comprising a plurality of metal elements joined to permit flexing of the cylindrical body along its longitudinal axis to permit the stent to conform to a curved body lumen, the improvement of the present invention comprises a polymeric film extending between the metal elements."); col. 2:40-44; col. 2: 49-53; col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:48-54; col. 3:58-col. 4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof."); col. 6:17-38; col. 8:8-9 ("The stent of claim 1 wherein the film comprises a therapeutic substance.").

Scott '928: Fig. 3; Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14 ("The present invention satisfies this need by providing a separate sleeve to encompass the stent and serve as a local drug delivery device to prevent thrombosis."); col. 4:53-55 ("The present invention satisfies this need by providing a separate sleeve to encompass a stent to locally administer drugs to prevent restenosis."); col. 4:58-68 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 5:26-29; col. 6:49-55 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject."); col. 8:23-54; col. 9:12-16 ("In addition, polymer-drug films which prevent thrombosis in the baboon and pig AV shunt system can be studied following stent-film placement in carotid, superficial femoral and coronary arteries following balloon injury of those vessels."); col. 10:24-33 ("In combination, a hollow tubular stent having a

predetermined length and a separate sheath removably encompassing at least a portion of said hollow tubular stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug."); col. 10:45-47 ("A method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath of claim 2 into a vessel of the subject."); col. 10:55-57 ("8. A method of promoting vascular cell growth in a subject comprising inserting a stent encompassed by the sheath of claim 6 into a vessel of a subject."); col. 11:1-3 ("11. A method of inhibiting vascular cell growth in a subject comprising inserting a stent encompassed by the sheath of claim 9 into a vessel of the subject."); col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:12-20 ("Stents are typically implanted within a vessel in a contracted state and expanded when in place in the vessel in order to maintain patency of the vessel to allow fluid flow through the vessel. Ideally, the implantation of such stents is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:42-50; col. 1:50-56 ("The stent can be used in coronary arteries or any other part of the vasculature or other body lumen where mechanical opening force is necessary or desirable to keep the vessel open or to maintain the stent flush against the lumen wall, and where an anti-restenosis, anti-proliferative or other types of therapeutic drug or agent is to be simultaneously positioned and diffused."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 1:64-2:2; col. 4:25-46; col. 5:4-9 ("The primary function of the sheet of polymeric material is to deliver therapeutic agents or drugs to help prevent thrombosis and/or restenosis."); col. 5:18-25; col. 5:49-6:25; col. 7:56-62 ("The

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elastic material attached over the coil of polymeric material helps keep the coil of drug loaded material snug on the stent structural member before it is expanded, and guides its linear expansion during inflation of a balloon dilatation catheter used for deployment of the stent and polymeric drug loaded material in the vasculature or other body lumen of a patient."); col. 9:3-18; col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:52-62 ("The invention provides prostheses which may be inserted into a lumen of a body and fixed to the lumen wall adjacent an area needing treatment. . . . [T]he methods and devices of the invention are also suited to treatment of any body lumen, including vas deferens, ducts of the gall-bladder, prostate gland, trachea, bronchus and liver or any other lumen of the body where medication cannot be applied without a surgical procedure."); col. 2:7-16 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:25-27 ("The current invention contemplates the usage of any prosthesis which elutes drugs locally to treat a lumen in need of repair."); col. 6:36-38; col. 11:47-48; 11:50-53.

Berg '354: Page 2:3-4 ("This invention relates to intravascular stents for treatment of injuries to blood vessels and particularly to stents having a framework onto which a therapeutic substance or drug is applied."); p. 2:14-18 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen. Examples of stents which have been successfully applied over a PTCA balloon and radially expanded at the same time as the balloon expansion of an affected artery include the stents disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) which are incorporated herein by reference in their entirety."); p. 3:16-18 ("In operation, the stent made according to the present invention can deliver drugs to a body lumen by introducing the stent transluminally into a selected portion of the body lumen and radially expanding the stent into contact with the body lumen."); p. 3:29-31; p. 5:53-6:1; p. 6:6-11; p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Abstract ("A stent made of biodegradable material includes a drug that is released at a rate controlled by the rate of degradation of the biodegradable material."); col. 2:55-56 ("The present invention includes a biodegradable stent for insertion into a lumen of a vessel in a living being."); col. 3:9-11 ("The stent releases drugs into a tubular vessel having a lumen in a living being."); col. 4:46-64; col. 5:11-20; col. 6:9-28; col. 6:65-7:1; col. 7:32-3.

Ding '536: Col. 1:29-32 ("The invention is particularly in terms of coatings on therapeutic expandable stent prostheses for implantation in body lumens, e.g., vascular implantation."); col. 1:34-45; col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for

coating the surfaces of prostheses such as deployable stents."); col. 5:10-56; col 13:13-26 ("A medical device having at least a portion which is implantable into the body of a patient, wherein at least a part of the device portion is metallic and at least part of the metallic device portion is covered with a coating for release of at least one biologically active material . . .").

Dinh '227: Abstract ("An intraliminal stent comprising fibrin and an elutable drug is capable of providing a treatment of restenosis."); col. 1:11-13 ("This invention relates to a method for lessening restenosis of body lumens and to intraliminal stents having anti-thrombosis and anti-restenosis properties."); col. 1:32-35; col. 2:35-37; col. 2:62-66; col. 6:19-22 ("The drug, fibrin and stent can then be delivered to the portion of the body lumen to be treated where the drug may elute to affect the course of restenosis in surrounding luminal tissue."); col. 8:20-27 ("The term 'stent' herein means any device which when placed into contact with a site in the wall of a lumen to be treated, will also place fibrin at the lumen wall and retain it at the lumen wall. This can include especially devices delivered percutaneously to treat coronary artery occlusions and to seal dissections or aneurysms of splenic, carotid, iliac and popliteal vessels."); col. 12:24-28.

Domb '055: Abstract ("Devices are provided having a polymer coating incorporating compounds inhibiting inflammation and infection, along with subsequent tissue growth onto and around the device. Preferred embodiments include catheters, tubes and implants that abut tissue following implantation into the body . . ."); col. 1:12-18 ("This invention relates to invasive medical devices for delayed/sustained release of pharmaceutical compositions from a polymer that is coated or incorporated into the devices. The purpose of the coating or delivery system on these devices is to reduce, control or even prevent the inflammation and infection that occur with prolonged use of these devices."); col. 4:15-17; col. 4:22-32; col. 5:24-6:18; col. 6:24-26; col. 11:27-38 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Abstract; col. 1:64-2:5; col. 2:9-21; col. 2:48-65; col. 3:55-67; col. 16:16-22; col. 31:62-64; col. 36:21-31; col. 37:34-38; col. 37:66-38:9; col. 49:27-31.

Hunter '981: Col. 1:12-17 ("The present invention relates generally to compositions and methods for treating cancer and other angiogenic-dependent diseases, and more specifically, to compositions comprising anti-angiogenic factors and polymeric carriers, stents which have been coated with such compositions, as well as method for utilizing these stents and compositions."); col. 3:39-45; col. 4:14-5:36; col. 7:12-16 ("Fig. 13 is an illustration of a representative embodiment of hepatic tumor embolization. Fig. 14 is an illustration of the insertion of a representative stent coated with an anti-angiogenic composition."); Fig. 13; Fig. 14; col. 12:23-35; col. 16:31-56; col. 17:63-18:7 ("[T]he anti-angiogenic compositions of the present invention may be formed as a film. . . . Such films are preferably flexible with a good tensile strength . . . and has controlled permeability."); col. 22:3-7; col. 23:6-13 ("[M]ethods are provide for

expanding the lumen of a body passageway, comprising inserting a stent into the passageway, the stent having a generally tubular structure, the surface of the structure being coated with an anti-angiogenic composition . . . such that the passageway is expanded."); col. 23:46-51; col. 24:45-51; col. 24:66-25:5; col. 25:24-29; col. 25:48-54; col.84:63-85:4; col. 86:56-59; col. 87:11-22; col. 88:19-26; col. 87:1-2.

Kinsella '608: Col. 6:8-12 ("Each of the aforementioned applications may also be amendable to selective, localized application of sustained-release preparations of taxol (or other microtubule-stabilizing agent) which would enable high dosage local drug delivery with little systemic toxicity."); col. 11:14-24 ("Ultimately, local sustained-release delivery systems may offer the best solution to prevent restenosis post-angioplasty, enabling high local concentrations of drug delivery and essentially eliminating problems of systemic toxicity. Drug delivery systems that can be valuable include drug-impregnated polymer-coated metallic stents [and] biodegradable drug-eluting polymer stents . . . ").

Kowligi '782: Abstract ("The elastomeric coating is made of polyurethane or another biocompatible non-porous elastomers and precludes tissue ingrowth into the outer cylindrical wall, minimizes suture hold bleeding, and increases suture retention strength, while reducing the incidence of serous weepage."); col. 1:18-26 ("The present invention relates generally to prosthetic vascular grafts for implantation within the vascular system of a patient, and more particularly, to a prosthetic vascular graft made from expanded, porous polytetrafluoroethylene (PTFE) tubing that is fabricated to retain the porous inner cylindrical wall of conventional PTFE vascular grafts, but wherein the outer cylindrical wall of the PTFE tube is rendered non-porous over at least a portion of its length."); col. 4:16-27; col. 10:18-24; col. 10:33-42; col. 10:51-59.

Lambert '922: Abstract; col. 2:16-35 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); col. 2:62-67 ("In accordance with yet another embodiment of the present invention, there is provided a method for the localized delivery of biologically active compounds to a subject. This invention method comprises implanting the above-described delivery system at a site where the targeted release of said biologically active compound is desired."); col. 3:8-12; col. 3:29-32; col. 3:50-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected)."); col. 7:29-32; col. 10:54-56; col. 12:40-42; col. 13:10-12.

Lambert '308: Abstract; p. 3:10-31 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); p. 4:25-31 ("In accordance with yet another embodiment of the present invention, there is provided a method for the localized delivery of biologically active compounds to a subject. This invention method comprises implanting the above-described delivery system at a site where the targeted release of said biologically active compound is desired."); p. 6:15-20 ("Substrates suitable for use in the practice of the present invention include metallic stents, such as vascular, biliary or ureteral stents, heart valves, metallic prostheses, prosthetic joints, pacemakers, catheters, balloon coatings, ocular implants, contact lenses, and the like."); p.6:21-

28 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected)."); claim 1:1-4; claim 19:1-3; claim 20; claim 27:1-5.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8.

Mitchell '711: Col. 3:24-31 ("This invention provides a method of preventing or treating hyperproliferative vascular disease in a mammal in need thereof by administering an antiproliferative effective amount of a combination of rapamycin and heparin to said mammal . . . via a vascular stent impregnated with a combination of rapamycin and heparin."); col. 7:16-20 ("Rapamycin in combination with heparin can be administered intravascularly or via a vascular stent impregnated with rapamycin in combination with heparin, during balloon catheterization to provide localized effects immediately following injury."); col. 7:56-8:7; col. 8:22-23; col. 8:39-42; col. 8:49-56.

Morris '781: Col. 3:45-50 ("This invention provides a method of preventing or treating hyperproliferative vascular disease in a mammal in need thereof by administering an antiproliferative effective amount of rapamycin to said mammal . . . via a vascular stent impregnated with rapamycin."); col. 11:41-45 ("Rapamycin, alone or in combination with mycophenolic acid can be administered intravascularly or via a vascular stent impregnated with rapamycin, alone or in combination with mycophenolic acid, during balloon catheterization to provide localized effects immediately following injury."); col. 12:29-35 ("A method of treating restenosis in a mammal . . . which comprises administering an antirestenosis effective amount of rapamycin to said mammal . . . via a vascular stent impregnated with rapamycin."); col. 12:36-42.

Morris '182: Page 3:24-27 ("This invention provides a method of preventing or treating hyperproliferative vascular disease in a mammal in need thereof by administering an antiproliferative effective amount of rapamycin to said mammal . . . via a vascular stent impregnated with rapamycin."); p. 7:27-29 ("Rapamycin, alone or in combination with mycophenolic acid can be administered intravascularly or via a vascular stent impregnated with rapamycin, alone or in combination with mycophenolic acid, during balloon catheterization to provide localized effects immediately following injury."); p. 7:57-8:1 ("Use as claimed in Claim 1 in which the medicament is adapted for administration . . . via a vascular stent impregnated with rapamycin."); p. 8:8-9 ("A use or product according to any one of Claims 1 to 4 wherein the hyperproliferative vascular disease is selected from intimal smooth muscle cell hyperplasia, restenosis, and vascular occlusion."); col. 8:15-16.

Myler '563: Abstract; col. 1:11-12 ("The present invention relates to cardiovascular stents which can be inserted into a body lumen."); col. 2:20-22; col. 2:53-58; col. 3:13-15; col. 4:56-57; col. 5:24-26 ("One purpose of the temporary stent is to modify the healing response to

prevent re-occlusion of the artery (restenosis).); col. 12:28-33; 12:63-65; col. 19:18-30 ("A tubular stent for implantation within a body lumen . . ."); col. 20:33-49; col. 20:51-52.

Palmaz '417: Abstract; col. 1:17-23 ("The invention relates to an expandable intraliminal graft for use within a body passageway or duct and, more particularly, expandable intraliminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease; and a method and apparatus for implanting expandable intraliminal grafts."); col. 4:25-37; col. 5:1-20; col. 5:26-43; col. 6:20-54; col. 11:3-34; col. 13:20-40; col. 14:39-59; col. 15:19-40; col. 15:53-16:5; col. 16:18-34; col. 16:43-63.

Aebischer '486: Abstract; Fig. 1; col. 3:19-23; col. 3:56-63; col. 5:29-43; col. 6:39-40; col. 8:1-30; col. 9:18-10:3.

Folkman '560: Col. 2:43-68; col. 3:18-23; col. 6:61-7:2; col. 10:11-14; col. 11:41-47; col. 11:56-12:20.

Schiraldi '243: Abstract; col. 1:8-21; col. 2:21-25 ("It is an object of this invention to provide an extruded film that is an effective and convenient intra-oral drug delivery system and method for applying and delivering controlled dosages of therapeutic agents into the oral cavity."); col. 2:30-51; col. 9:36-55.

Valentini '029: Abstract ("Medical devices employing semipermeable materials, such as acrylic copolymers, polyurethane isocyanate, and other biocompatible semipermeable polymers, are disclosed for use as guidance channels in regenerating nerves."); col. 2:29-57; col. 6:14-42.

Greco '135: Col. 3:8-19 ("An object of the present invention is to provide improved surfactant-modified implantable devices having a drug, including antibiotics, antithrombogenic agents, thrombolytic agents, disinfectants, etc., bound to the surface thereof."); col. 3:48-4:1; col. 9:10-12; col. 9:25-26.

Bawa '279: Col. 2:8-15 ("Another object is to provide a sustained-release polymeric hydrogel dosage form that is useful for topical, systemic or transdermal administration of medicinal agents, particularly ophthalmic drugs. A further object is to provide a polymeric matrix which is moldable to any desired shape, with moldability to the shape of the cornea of the eye being of major interest."); col. 8:50-53.

Wood '066: Abstract ("A controlled-release bandage containing therapeutic agents in a poly(vinyl alcohol) cryogel is disclosed. The bandage may include . . . hydrophobic particles to further insure controlled and constant release of therapeutic agents."); col. 2:56-66 ("Bandages comprising cryogel and therapeutic agents are used to provide a protective covering and to provide a controlled and uniform administration of therapeutic agents to sites of trauma such as wound, thermal or chemical burns, ulcers, lesions or surgical sites. Cryogel bandages may include . . . particles having hydrophobic properties, which absorb the therapeutic agent and release it in an uniform and controlled manner."); col. 2:67-3:10; col. 23:4-11.

Strecker '746: Abstract ("The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in

place."); col. 1:56-2:2; 2:12-15; col. 2:21-32; col. 5:34-54; col. 6:59-62; col. 7:16-35; col. 8:19-10:19.

Lambert '246: Abstract; col. 2:15-34; col. 3:55-4:35; col. 10:45-61; col. 11:34-12:12; col. 12:15-52.

Bellamkonda '029: Abstract; Fig. 6; col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 4:9-14; col. 10:64-11:13; col. 11:33-40; col. 12:17-25; col. 19:33-22:37.

Dayton '382: Abstract ("A minimally invasive bioactivated endoprosthesis device for vessel repair. The device comprises a stent which is formed from metal or polymers into a predetermined shape which includes a plurality of holes . . . to provide a desired bending modulus."); col. 1:9-17 ("The present invention relates to an improved percutaneously inserted endoprosthesis device which is permanently or temporarily implanted within a body vessel, typically a blood vessel."); col. 3:62-4:17; col. 5:50-53; col. 8:4-33.

Burt '036: p. 4:19-33; p.10:17-25; p.14:9-27 ("As noted above, anti-angiogenic compositions of the present invention comprise an anti-angiogenic factor and a polymeric carrier. In addition to the wide array of anti-angiogenic factors and other compounds discussed above, anti-angiogenic compositions of the present invention may include a wide variety of polymeric carriers, including for example both biodegradable and non-biodegradable compositions."); p.21:2-4; 21:25-22:6.

Goldin '568: Abstract; col. 1:43-62; col. 2:1-6 ("In other instances, among them the release from the walls of cylindrical nerve guide tubes of trophic factors believed to aid nerve regeneration . . . it may be desirable for such an implantable delivery device to slowly decompose in vivo."); col. 2:24-29; col. 4:48-57 ("A preferred embodiment entails implantation of the device at or near the target of the desired therapeutic effect."); col. 10:55-58; col. 11:6-9; col. 23:6-26:5.

Palmaz '665: Abstract ("An expandable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 1: 11-17; col.2:64-3:7.

Palmaz '762: Abstract ("An expandable and deformable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 1:19-25; col. 4: 6-19.

Palmaz '337: Abstract ("An expandable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 1: 24-30; col. 3: 1-12.

Zaffaroni '254: Abstract ("A drug delivery device for administering a drug at a controlled rate for a prolonged period of time to produce a local or systemic physiological or pharmacological effect is comprised of a wall surrounding a reservoir containing a drug."); col. 4: 15-17 ("FIG. 4 is a side, fragmentary view depicting an anal drug delivery device of the invention for releasing drug in a body orifice."); col. 4: 21-28; Figures 4 and 6; col. 5: 65-68; col. 7: 1-5.

Aebischer: p. 283 (disclosing use of ethylene-vinyl acetate copolymer), p. 284-5 (disclosing implantation into human or animal tissue to promote nerve regeneration).

Dev: p. 273-74 (disclosing implantation of a polymer-coated stent capable of releasing treatment material).

Claim 8 [8B] (cont'd): providing a device including, a layer of flexible material that is minimally porous to macromolecules, said layer having a first and second major surface, the layer being capable of shaping in three dimensions by manipulation by human hands,

Where Found in the Prior References

Peterson '166: Col. 2:51-54 ("Typical polymeric carriers are polyesters, polyamides, polyurethanes and other condensations polymers . . .").

Schwartz '823: Abstract ("The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen."); Figs. 6-9, 13, 15; col. 1:9-14; col. 1:17-19; col. 1:53-55; col. 2:16-19 ("It is therefore an object of the present invention to provide a stent having longitudinal flexibility which allows it to conform to curves and variation in body lumens."); col. 2:29-40; col. 2:44-49; col. 2:49-53; col. 3:48-57; col. 3:58-61 ("The improvement of the present invention includes applying to the above-mentioned type of stent a flexible or elastomeric polymeric film which extends between the metal elements."); col. 3:64-4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof."); col. 4:20-27; col. 4:49-5:41; col. 5:64-6:1; col. 6:17-20; col. 6:30-32; col. 6:43-47; col. 49-52; col. 6:58-68 ("The flexible film can be applied as a sheath to the metal stent elements after which the stent can be compressed, attached to a catheter, and delivered through the body lumen to a desired location."); col. 7:25-8:11 ("The resulting stent has microcapsules containing one therapeutic substance on the inside (and able to contact blood once implanted in a blood vessel) and

microcapsules containing a second therapeutic substance on the outside (and able to contact the vessel wall when implanted in contact with the vessel wall."); col. 8:19-41.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); Fig. 3; col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-29; col. 5:34-6:29; col. 6:37-41; col. 6:41-45 ("Modifications of the polymer coating include a ring that encompasses the proximal portion of the stent, single or multiple strips that cover a portion of the stent, or a polymer coating with perforations."); col. 7:55-59; col. 8:23-60 ("Ethylene vinyl acetate copolymer (EVA) (Catalog #34,691-8) was obtained from Aldrich Chemical Company, Inc. (Milwaukee, Wis.); col. 10:24-33; col. 12:1-6; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow Controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Fig. 3; col. 1:7-10 ("This invention relates generally to expandable intraliminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:15-19 ("Ideally, implantation of such stent is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 1:57-60 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member."); col. 1:64-2:2 ("The polymer material can be a thermoplastic or an elastomer, for example, so that the film can stretch or deform radially when the stent structural member is expanded. The film of polymer material can be formed as a solid sheet, or can incorporate holes of various sizes and shapes to promote rapid endothelialization."); col. 2:23-33;

col. 2:48-55; col. 4:15-24; col. 4:25-46; col. 4:47-5:3; col. 5:4-10; col. 5:49-6:25 ("The polymeric material is preferably selected from thermoplastic and elastomeric polymers. . . . In another currently preferred embodiment, the polymeric material can be ethylene vinyl acetate (EVA) . . ."); col. 6:26-65; col. 6:66-col.7:7; col. 7:18-21 ("The apertures also improve the flexibility of the polymeric material, allowing the stent segment to be more easily rolled and uncoiled during expansion of the stent structural member . . ."); col. 7:23-42; col. 7:63-65; col. 8:12-57; col. 9:5-12; col. 10:12-30; col. 10:40-47.

Wolff '208: Col. 2:7-16 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); 2:28-30 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 6:59-62 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously. The polymer may be biostable or bioabsorbable. If biostable, the drug would diffuse out of the polymer."); col. 6:64-67 ("The variations of design shown in the embodiments of Figs. 1 and 2 show that the prosthesis of the invention must be secured against a lumen wall and must carry a drug-eluting polymer."); col. 7:59-61; col. 9:23-33 ("That layer may be a simple barrier which limits diffusion of drugs in the polymer. In that event, the smaller molecules could elute out immediately, while larger compounds would not elute until later when the layer has biodegraded."); col. 9:39-42 ("The device is fixed into place either by radial expansion in devices such as shown in Fig. 1 or are deformed by a balloon catheter in the case of devices in accordance with Fig. 2."); col. 10:3-45 ("The stents are arranged on the distal end of the catheter such that the catheter can provide remote, transluminal deployment of the stents, with the metal stent inside the polymeric stent, from an entry point into a selected portion of the body lumen to be treated and also remote actuation of an expansion mechanism from the proximal end of the catheter. The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen."); col. 10:51-57; col. 10:66-11:3 ("The metal stent is crimped onto the balloon and includes an elongated lead extending to the proximal end of the catheter assembly where it includes an enlarged portion to enable an operator to securely grip the lead."); col. 11:50-53 ("(b) a body including a plurality of support elements forming an open-ended, radially expandable, self-supporting tubular structuring having an interior surface and an exterior surface."); col. 12:1-15; col. 12:37-40 ("8. The device of claim 1 also comprising a barrier coating of polymeric material on the drug-containing filament to limit the rate of drug elution.").

Berg '354: Page 2:14-15 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen."); p. 2:43-54 ("Viewed from a further aspect the invention provides the use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug-eluting surface coating."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a

therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p.3:18-22 ("The transluminal delivery can be accomplished by a catheter designed for the delivery of stents and the radial expansion can be accomplished by balloon expansion of the stent, by self-expansion of the stent, or a combination of self-expansion and balloon expansion. Thus the present invention provides a stent which may be delivered and expanded in a selected blood vessel without losing a therapeutically significant amount of a drug applied thereto."); p. 3:29-31 ("Also, stents made with biostable or bioabsorbable polymers such as poly(ethylene terephthalate), polyacetal, poly(lactic acid), poly(ethylene oxide)/poly(butylene terephthalate) copolymer could be used in the present invention. "); p. 3:33-34 ("Both the inner and outer surfaces of the stent may be provided with the coating according to the present invention."); Table 1; p. 4:5-24; p. 5:28-29; p. 6:6-11; p. 6:15; p. 6:24-35; p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Col. 1:58-60; col. 2:16-17; col. 3:21-25 ("The tubular main body includes an outer surface and inner surface. The outer surface of the main body faces an inner surface wall of the vessel. The inner surface of the stent faces a stream flowing through the lumen as shown in cross section in Fig. 2."); col. 4:1-5 ("In one embodiment, the main body includes a film that is preferable combined with the plurality of fibers disposed around the main body. The film combined with the plurality of fibers defines the outer surface of the main body."); col. 4:15-16 ("Preferable, the main body of the stent includes a film covering the inner surface."); col. 4:19-22 ("Additionally, the present invention includes an embodiment where the inner surface and the outer surface of the main body are separated by at least one interior film layer."); col. 5:23-33 ("For instance, in one embodiment, the film and fibers covering the inner surface of the main body of the biodegradable stent The film covering the outer surface along with the plurality of fibers"); col. 4:46-64; col. 5:11-20; col. 6:49-59; col. 7:10-20 (" . . . said tubular main body including a slot extending lengthwise through the main body and defined by opposing edges of the main body wherein the opposing edges must be moved toward each other under compression in order to transport the biodegradable stent through a vessel of a living being . . ."); col. 7:27-29; col. 8:18-24; Fig. 2.

Ding '536: Abstract ("The coating includes a relatively thin layer of biostable elastomeric material containing an amount of biologically active material, particularly heparin, dispersed in the coating in combination with a non-thrombogenic surface."); col. 1:24-29 ("The present invention relates generally to providing biostable elastomeric coatings on the surfaces of implants which incorporate biologically active species having controlled release characteristics in the coating particularly to providing a non-thrombogenic surface during and after timed release of the biologically active species."); col. 1:48-51 ("One type of self-expanding stent has a flexible tubular body formed of several individual flexible thread elements each of which extends in a helix configuration with the centerline of the body serving as a common axis."); col. 3:5-9; col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 3:56-64 (" . . . the tubular body is formed of a self-expanding

open braid of fine, single or polyfilament metal wire which flexes without collapsing, readily axially deforms to an elongate shape for transluminal insertion via a vascular catheter and resiliently expands toward predetermined stable dimensions upon removal in situ."); col. 5:10-56 ("Polymers generally suitable for the undercoats or underlayers include silicones (e.g., polysiloxanes and substituted polysiloxanes), polyurethanes, thermoplastic elastomers in general, ethylene vinyl acetate copolymers, polyolefin elastomers, polyamide elastomers, and EPDM rubbers. The above-referenced materials are considered hydrophobic with respect to the contemplated environment of the invention."); col. 12:62-13:2; col. 13:13-26; col. 13:37-40; col. 14:5-17; col. 14:22-34.

Dinh '227: Figs. 1, 9, 10; col. 1:32-35 ("The stent is typically inserted by catheter into a vascular lumen told [sic] expanded into contact with the diseased portion of the arterial wall, thereby providing mechanical support for the lumen."); col. 2:51-54 ("To accomplish this while not affecting the strength of the overall fibrin stent structure, a first layer is applied to a stent body, the first layer incorporating a polymer and the therapeutic substance."); col. 2:62-66 ("The inclusion of a polymer in intimate contact with a drug on the underlying stent structure allows the drug to be retained on the stent in a resilient matrix during expansion of the stent and also slows the administration of drug following implantation."); col. 3:10-14; col. 3:14-22; col. 3:25-38; col. 5:3-7; col. 5:44-55; col. 5:56-57; col. 6:13-19 ("In U.S. Pat. No. 4,548,736 issued to Muller et al., a dense fibrin composition is disclosed which can be a bioabsorbable matrix for delivery of drugs to a patent. Such a fibrin composition can also be used in the present invention by incorporating a drug or other therapeutic substance useful in diagnosis or treatment of body lumens to the fibrin provided on the stent."); 6:50-56 ("Alternatively . . . a dense fibrin composition suitable for drug delivery can be made without the use of microcapsules by adding the drug directly to the fibrin followed by compression of the fibrin into a sufficiently dense matrix that a desired elution rate for the drug is achieved."); col. 6:62-67; col. 7:10-13; col. 7:13-2; col. 7:56-64 ("In another embodiment of the invention, the coating of polymer and drug on the stent is achieved by forming a first fibrin layer on the stent body which incorporates the therapeutic substance and then applying a second layer of fibrin."); col. 8:49-52 ("A catheter has a balloon upon which a stent has been placed, the stent having a deformable metal portion and a fibrin coating, thereon."); col. 8:52-60 ("Fig. 2 shows an alternative stent in which a fibrin film has been affixed to the underlying metallic framework by affixing it to the stent . . ."); col. 8:64-9:3; col. 9:18-24; col. 9:49-50 ("The resulting fibrin stent includes the stent embedded in a very thin elastic film of fibrin."); col. 9:59-63; col. 12:24-28; col. 12:38-50.

Domb '055: Abstract ("Devices are provided having a polymer coating incorporating compounds inhibiting inflammation and infection, along with subsequent tissue growth onto and around the device. . . . Preferred polymeric coating are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); col. 1:12-15 ("This invention relates to invasive medical devices for delayed/sustained release of pharmaceutical compositions from a polymer that is coated or incorporated into the devices."); col. 3:54-57 ("In the preferred embodiments, these have utilized bioerodible polymers as the matrix for the drug to be released, usually as a function of diffusion and erosion of the polymer."); col. 4:22-36; col. 5:24-37 ("In a particularly preferred embodiment, polymers incorporating steroids are coated onto devices including tracheal T-tubes, stoma stents, laryngeal/bronchial stents, laryngeal keels, and nasogastric tubes."); col. 5:41-45;

col. 5:46-6:1; col. 6:24-26 ("Examples of suitable polymers include ethylene vinyl acetate, polyurethane, silicones, hydrogels, polyurethane, and polyvinyl chloride."); col. 7:10-20; col. 7:40-52; col. 9:15-30; col. 9:55-10:2; col. 10:21-52; col. 10:60-11:11; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 11:36-38 ("The medical device of claim 1, wherein the polymer is selected from the group consisting of polyurethane, ethylene vinyl acetate, silicones, hydrogels, and polyvinyl chloride."); col. 11:39-44; col. 12:11-22; col. 12:23-25; col. 12:26-31; col. 12:32-42.

Fox '096: Abstract ("A method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers, and antimicrobial agents . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 2:48-65; col. 3:55-67 ("The polymeric coating agent component of the coating vehicle of the present invention is selected from the group consisting of biomedical polyurethanes, biomedical silicones, biodegradable polymers and combinations thereof."); col. 3:55-67; col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages."); col. 19:11-16; col. 31:62-64.

Hunter '981: Fig. 14B, 17E; col. 1:12-17; col. 3:42-45 ("Within one aspect of the present invention, compositions are provided (anti-angiogenic compositions) comprising (a) an anti-angiogenic factor and (b) a polymeric carrier."); col. 3:53-61; col. 12:23-25 ("As noted above, the present invention provides compositions comprising an anti-angiogenic factor, and a polymeric carrier."); col. 16:31-56; col. 17:63-18:7 ("[T]he anti-angiogenic compositions of the present invention may be formed as a film. . . . Such films are preferably flexible with a good tensile strength . . . and has controlled permeability."); col. 22:3-7; col. 22:21-39; col. 22:40-64; col. 22:54-58; col. 23:26-30; col. 47:58-49:7; col. 52:4-8; col. 60:35-45; col. 66:13-22; col. 69:19-62; col. 84:62-86:24; 86:56-59; col. 87:11-22; col. 88:19-26.

Kowligi '782: Abstract ("The elastomeric coating is made of polyurethane or another biocompatible non-porous elastomers and precludes tissue ingrowth into the outer cylindrical wall, minimizes suture hold bleeding, and increases suture retention strength, while reducing the

incidence of serous weepage."); Figs. 2 & 3; col. 1:18-26; col. 1:28-41; col. 1:42-64; col. 2:15-20; col. 2:38-47; col. 2:53-59; col. 2:60-3:4 ("PTFE tube 32 includes an inner cylindrical wall and an opposing outer cylindrical wall. As shown in Fig. 2, outer cylindrical wall is coated entirely around its circumference by a uniformly thick coating of a biocompatible elastomer."); col. 3:27-38; Figure 3; col. 4:1-5; col. 4:16-27 ("In regard to elastomeric coating 38 shown in Fig. 2, such elastomeric coating is selected to be a biocompatible elastomers and may be selected from the group consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 4:28-37; col. 4:37-39 ("The elastomeric coating should also be sufficiently non-porous to preclude serous weepage and inhibit tissue ingrowth therethrough."); col. 4:64-66; col. 5:4-7; col. 7:49-8:9; col. 8:38-44; col. 9:65-10:6; col. 10:18-24; col. 10:33-42; col. 10:43-50; col. 10:51-59; col. 10:60-67.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 2:16-35; col. 2:40-50; col. 3:8-12; col. 3:29-32; col. 3:54-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); col. 5:57-61; col. 7:29-32; col. 8:1-6; col. 10:57-64; col. 11:49-51; col. 11:65-12:13; col. 12:43-64; col. 13:13-19.

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p. 3:10-31 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); p. 4:2-12; p. 6:21-28 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); p. 10:17-21; claim 1:1-14; claim 8:1-5; claim 10:1-3; claim 11; claim 22; claim 23:1-14; claim 19:4-31.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8.

Myler '563: Abstract; Figs. 1, 2, 13; col. 2:10-13; col. 2:13-16 ("The stent is configured to permit radial expansion, such as under the force generated by balloon dilation, and radial contraction in response to axial elongation."); 2:22-26; col. 2:27-28; col. 3:13-15; col. 3:33-34; col. 3:44-46; col. 3:48-51 ("Alternatively, tubular stents formed from flexible non-metal

materials such as elastomeric polymers or rubber (latex) can also be radially reduced by axial elongation in accordance with the present invention."); col. 3:52-54; col. 3:58-61; col. 4:9-12; col. 4:30-43 ("In a preferred embodiment, the interior and exterior walls of stent 10 are enclosed in a thin polymeric envelope. . . . Suitable envelope materials include elastic materials such as latex and others that can be readily selected by one of skill in the art."); col. 4:53-56; col. 5:1-16; col. 5:39-41 ("For the above reasons, even the expanded pores for drug delivery should be small enough to maximize or prevent cell penetration, but large enough for drug delivery."); col. 5:50-54; col. 11:63-65; col. 12:11-13; col. 12:19-23; col. 12:28-33 ("Suitable materials include elastomeric polymers or natural rubber (latex). . . . Polymeric stents can be provided with relatively fluid impenetrable walls, or porous walls such as to allow drug delivery, as will be apparent to one of skill in the art."); col. 12:54-62; col. 12:63-65 ("Suitable coating materials include elastic materials such as polyethylene or PET or other materials that can be readily selected by one of skill in the art."); col. 18:51-19:9; col. 19:18-30; col. 19:31-32; col. 19:61-63; col. 19:65-20:7; col. 20:51-57.

Palmaz '417: Fig. 1A, 1B, 3, 5, 6, 8; Col. 5:66-68 ("Figs 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon"); col. 11:3-14 ("Examples of a suitable biologically compatible coating would be porous polyurethane, Teflon™ or other conventional biologically insert plastic materials."); col. 11:3-34 ("The coating should be thin and highly elastic so as not to interfere with the desired expansion and deformation of prosthesis, or graft. . . . Examples of biologically compatible coatings would include coatings made of absorbable polymers such as those used to manufacture absorbable sutures. Such absorbable polymers include polyglycoides, polyacoides, and copolymers thereof."); col. 13:22-24; col. 13:30-40.

Tice '330: Col. 3:20-33 ("Suitable wall forming materials include polystyrene, ethylcellulose, cellulose acetate, hydroxyl propylmethylcellulose phthalate, cellulose acetate, dibutylaminohydroxypropyl ether, polyvinylbutyral, polyvinyl formal, poly(meth)acrylic acid ester, polyvinylacetal-diethylamino acetate, 2-methyl-5-vinyl pyridine methacrylate-methacrylic acid copolymer, polycarbonate, polyesters, polypropylene, vinylchloride-vinylacetate copolymer, polysaccharides, glycerol distearate, and the like. A preferred group of polymeric wall forming materials includes those which are biodegradable such as aliphatic polyesters including polylactide, polyglycolide, polycaprolactone and copolymers thereof."); col. 8:38-51.

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); Figs. 1 & 2; col. 3:7-18; col. 3:56-63; col. 4:31-34 ("The outer membrane surface is nonporous, while porous inner membrane surface allows for the diffusion therethrough of active factor 26."); col. 5:18-28 ("In a preferred embodiment of the invention, the outer surface of the membrane is impermeable to solutes of any size, while the inner membrane surface contains pores [that] enable the active factors to diffuse out of the membrane and into the lumen of the channel."); col. 6:17-22 ("The layering procedure allows deposition of an impermeable coat on the outer surface of the device, insuring that the active factors incorporated into the membrane walls will be inhibited from diffusing through the external surface, and will

diffuse only through the inner membrane surface into the lumen of the channel."); col. 6:54-61; col. 9:18-10:3.

Folkman '560: Col. 2:43-68 ("A biocompatible plastically deformable polymer matrix . . . substantially impermeable to a macromolecule"); col. 3:18-23 ("The polymer matrixes, which are suitably used in the present invention, are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:36-51 ("Typical polymeric material suitable for forming the matrix . . . include . . . alkylene-vinyl acetate copolymers . . . crosslinked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:52-4:26 ("In the presently preferred embodiment the polymeric materials useful for forming the matrix are the ethylene vinyl ester copolymers of the general formula . . ."); col. 11:56-12:20.

Cohen '496: Col. 3:26-45 ("The polymer matrices . . . are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 9:40-10:17; col. 10:18-32.

Schiraldi '243: Col. 1:8-21 ("The extruded film drug delivery system of the present invention, which has incorporated therein the medicament to be dispensed, is so thin and flexible when wet as to be unobtrusive to the patient after it has been properly positioned and placed in the mouth."); col. 1:58-60; col. 2:30-51; col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. . . . The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 9:36-55; col. 10:12-18; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Valentini '029: Abstract ("Medical devices employing semipermeable materials, such as acrylic copolymers, polyurethane isocyanate, and other biocompatible semipermeable polymers, are disclosed for use as guidance channels in regenerating nerves. . . . The guidance materials are chosen such that they are capable of allowing the diffusion of nutrients and other metabolites to the regenerating nerve site while excluding fibroblasts and other scar-forming cells."); Fig. 3; col. 1:56-2:4; col. 2:29-57 ("It has been discovered that the repair of severed or avulsed nerves can be greatly enhanced by the use of selectively permeable polymeric materials as nerve guidance channels. . . . The devices can be formed from various polymeric materials, such as acrylic copolymers, polyvinylidene fluoride or polyurethane isocyanate Preferable, the materials allow passage therethrough of solutes having a molecular weight of about 100,000 daltons or less. . . . The nerve guidance channels of the present invention are also preferably designed to retain nerve growth factors secreted at the anastomatic site or seeded therein, as well as retain any luminal matrix material placed inside the guidance channels."); col. 2:58-3:14; col.

3:62-67; col. 4:46-59; col. 5:13-32 ("The success rate and quality of peripheral nerve regeneration was dramatically enhanced through the use of a semipermeable material."); col. 5:33-41; col. 5:42-6:12 ("The permselective characteristics of the inner membrane allow the exchange of nutrients, while concentrating growth factors released by the nerve and excluding scar-forming cells."); col. 6:14-24; col. 6:31-42.

Greco '135: Col. 3:48-4:1 ("These devices will consist of organic polymers and/or metallic materials including: . . . polyethylene . . . elastomeric organosilicon polymers, such as polysiloxanes, e.g. Silastic ®").

Aebischer '627: col. 3:57-4:3 ("The polymeric insert includes pores having a molecular weight exclusion of from about 1 kD to about 1,000 kD, but preferably from about 25kD to about 100 kD."); col. 4:11-27 ("The terms 'semipermeable' is used herein to describe biocompatible membranes that allow the diffusion therethrough of molecules having a relatively low molecular weight, while excluding the passage of those having a relatively high molecular weight. . . . The semipermeable membrane can be made of various polymeric compositions such as polyvinylchloride, polyacrylonitrile, polyvinylidene fluoride, polystyrene, polymethylmethacrylate, polysulfone, and acrylic copolymers."); col. 7:57-8:14 ("In this embodiment, a semi-permeable membrane functions as a protective cell culture device for the neurotransmitter-secreting cells. The pores of the membrane should be large enough to enable the exchange of metabolites with body fluids, and to permit the diffusion therethrough of neurotransmitter produced by the cells therein, but are small enough to bar the passage therethrough of larger elements deleterious to the cells."); col. 13:31-48; col. 13:66-68; col. 14:1-2; col. 14:22-28; col. 14:54-56.

Bawa '279: Col. 6:50-57 ("Alternatively, a two layer system may be formed having one layer as polymer plus drug and the other layer as drug-free polymer.").

Wood '066: Abstract ("A controlled-release bandage containing therapeutic agents in a poly(vinyl alcohol) cryogel is disclosed. The bandage may include . . . hydrophobic particles to further insure controlled and constant release of therapeutic agents."); col. 2:56-3:17; col. 7:51-65; col. 17:19-22; col. 17:30-34 (" . . . to give a flexible, elastomeric, white cryogel membrane . . ."); col. 18:1-4; col. 18:13-16; col. 18:26-30; col. 23:4-11.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); Figs. 4, 7, 8; col. 1:12-22 ("Once correctly positioned it will expand from an initial state with a narrow lumen into a state with a lumen that is as wide as its placement will allow. . . . The lumens can be expanded by mechanically stretching them with a known balloon catheter. They can also be compressed prior to implantation and stretch out on their own subject to the resilience introduced by the compression."); col. 1:63-2:2; col. 2:12-15 ("The present invention on the other hand exploits a wrapping material that plastically deforms as it expands . . ."); col. 2:21-32; col. 2:33-38; col. 2:59-64; col. 2:65-3:4; col. 3:7-16; col. 3:27-33 ("The lining can to advantage be made of polymers or compounds thereof."); col. 3:51-62; col. 3:63-4:31 ("It can be of advantage for

the lining to be of several layers, each impregnated with different medications. . . . It has also been demonstrated practical for the inner layer of the lining to be impregnated with antithrombotics and the outer with antiproliferatives and/or other medicational substances.); col. 5:18-20 ("Fig. 4 is a view similar to that of Fig. 2 of an endoprosthesis with a multiple-layer lining and with its ends coated with medication,"); col. 5:34-41 ("The endoprosthesis . . . is completely enclosed in an inner lining component and an outer lining component."); col. 5:49-54 ("The thread itself in an endoprosthesis of the type illustrated in Fig. 3 can also be wrapped in a coat of medicated and biodegradable wrapping material. . . . The prosthesis can of course alternatively be enclosed in a flexible-tubular coat."); col. 5:55-64; col. 6:30-44; col. 6:50-55; col. 6:59-62; col. 7:16-35; col. 7:48-65; col. 8:4-8; col. 8:10-10:19.

Lambert '246: Abstract ("Thus, a polyurethane coating is applied to a prosthetic article, the coating then swelled . . . so that substantial quantities of biologically active compounds can be incorporated within the interstices of the polymer."); col. 2:15-34; col. 2:40-49; col. 2:53-65; col. 3:55-4:35 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility to as to enable the application of a stable coating onto substrate (i.e. the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected)."); col. 10:45-67; col. 11:34-59; col. 12:15-41.

Bellamkonda '029: Abstract ("A nerve guidance channel for use in regenerating severed nerve is prepared containing a tubular semi-permeable membrane having openings adapted to receive the ends of a severed nerve, and an inner lumen containing the matrix having an adhesive peptide fragment through which the nerve can regenerate."); Fig. 6; col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 4:9-14; col. 4:21-39 ("Any suitable hydrogel may be used as the substrate for the bioartificial extracellular matrices of this invention."); col. 4:48-57; col. 5:10-14 ("Several physical properties of the hydrogel matrices of this invention are dependent on gel concentration. Increase in gel concentration may change the gel pore radius, morphology, or its permeability to different molecular weight proteins."); col. 7:13-25; col. 10:28-40 ("Permselective channels with a molecular weight cut-off of 50,000 daltons allowed regeneration of nerves in a mouse sciatic nerve model."); col. 10:41-63; col. 10:64-11:13; col. 11:33-40; col. 12:13-16 ("Preferably the permselective membrane is fabricated to be impermeable to some of these substances so that they are retained in the proximity of the regenerating nerve ends."); col. 12:17-25 ("Briefly, various polymers and polymer blends can be used to manufacture the nerve guidance channel."); col. 12:42-49; col. 19:7-16; col. 23:54-24:55.

Dayton '382: Abstract ("The device comprises a stent which is formed from metal or polymers into a predetermined shape which includes a plurality of holes . . . to provide a desired bending modulus. The stent is then coated with a polymer . . . which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids, with the equilibrium being controlled by charge distribution, concentration and molecular weight of the bioactive substance in relation to the pore size of the polymeric carrier for controlled prolonged

release of said bioactive substance."); Figs. 4, 7, 9, 10, 12, 14; col. 3:62-4:17 ("Among these polymers are polymers having a microporous structure, such as . . . biodegradable polylactic acid polymers, polyglycolic acid polymers . . ."); col. 4:24-33 ("A bioactive substance is preferably admixed in the polymer for elution from the microporous structure of the stent or coating on the stent after implantation. The rate of elution of the bioactive substance is controlled by selecting a pore size for microporous structure . . ."); col. 4:42-50; col. 4:54-5:3; col. 6:64-7:7 ("The polymer should have a microporous structure with a predetermined pore size."); col. 8:18-33 ("a polymer forming the exterior surface of said stent for operative contact with said tissue . . ."); col. 8:42-59; col. 8:66-9:5; col. 10:1-2.

Burt '036: Fig. 14B; p. 4:19-33 ("Similarly a wide variety of polymeric carriers may be utilized, representative examples of which include poly(ethylene-vinyl acetate) . . . and copolymers of polylactic acid and polycaprolactone."); p. 10:17-25; p. 14:9-27 ("As noted above, anti-angiogenic compositions of the present invention comprise an anti-angiogenic factor and a polymeric carrier. In addition to the wide array of anti-angiogenic factors and other compounds discussed above, anti-angiogenic compositions of the present invention may include a wide variety of polymeric carriers, including for example both biodegradable and non-biodegradable compositions."); p. 21:2-4; p. 21:25-22:6 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size."); p. 51:1-52:35.

Goldin '568: Figs. 1A, 5A-5F; col. 1:43-62 ("Release by controlled diffusion may be accomplished by means of containment of the therapeutic agent within a substrate whose small pore size and/or tortuosity of diffusion path thereof limits the diffusion of said agent through the substrate. . . . The therapeutic agent can be incorporated within the diffusion-limiting substrate . . . Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:8-12; col. 2:24-29 ("Microporous membranes for release of proteins by controlled diffusion have been fabricated from ethylene vinyl acetate (EVA), and said membranes have been used in vivo in a manner which demonstrates their therapeutic potential."); col. 5:28-34 (" . . . underlayment material of controlled pore size can be created and used to fabricate a device of optimal porosity . . . and accessibility of the releasable macromolecule to biological material at or beyond the membrane's external surface . . ."); col. 11:58-12:14; col. 13:53-65; col. 14:1-28; col. 14:66-15:67; col. 31:57-32:7 ("The device of claim 1 wherein said microporous underlayment comprises a polymer."); col. 32:16-22.

Palmaz '665: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); Figures 5 and 6; col. 3:20-25 ("The present invention includes a tubular shaped member having first and second ends and a wall surface disposed between the first and second ends..."); col.3:47-51 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5:30-32 ("FIGS. 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon."); col. 5:58-63; col. 4:24-28.

Palmaz '762: Col. 3:34-37 ("The present invention includes a tubular shaped member having first and second ends and a wall surface disposed between the first and second ends..."); 3:65-4:2 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 4:43-46; col. 6:9-13; col. 9:20-25; col. 10:28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '337: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col. 3:27-30 ("The present invention includes a tubular shaped member having first and second ends and a wall surface disposed between the first and second ends..."); col.3:52-56 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 4: 29-34; col. 5:19-21; Figures 5 and 6; col. 8:28-32; col. 9:24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials."); col. 5:65-6:2.

Zaffaroni '254: Abstract ("The wall is formed in at least a part of a microporous material..."); col. 1:19-23 ("The wall of the device is comprised in at least a part of a microporous material..."); col. 3:5-10; col. 3:42-45 ("In accomplishing these objects and advantages of this invention, one feature of the invention, in its broadest aspect resides in a novel drug delivery device comprising a wall enclosing a reservoir."); col. 3:48-53; col. 4:41 ("Drug delivery device 10 is comprised of a wall 11..."); col. 4:47-54 ("Wall 11 is formed of a microporous material the micropores 15 of which contain a drug release rate controlling medium, not shown, permeable to the passage of drug, as by diffusion, or by convection, or by a concurrent operation of both, but the rate of passage of the drug through the medium in the micropores is lower than the rate of passage of drug through the solid drug carrier."); col. 5:3-11; col. 6: 27-30.

Engelberg & Kohn: p. 298; p. 299 ("Whilst L-PLA showed a purely elastic deformation for most of the stress-strain curve, D,L-PLA was more ductile and exhibited a significantly larger proportion of plastic deformation."); p. 301 ("Compression moulding [of PCL] yielded opaque, flexible films.") ("Transparent films [of PTMC] were readily obtained by compression moulding at 40 °C using a low load of 0.5 tonnes. The films could be rolled up and deformed without breaking.").

Aebischer: p. 283 (disclosing preparation of polymer tube made of ethylene-vinyl acetate copolymer); Fig. 2A (disclosing one major surface facing the nerve stumps and another major surface facing away from the nerve stumps); p. 284 (disclosing manipulation of polymer tube to allow entry of nerve stumps).

Dev: p. 273 ("We used a commercially available biomedical grade polyurethane Tecoflex is a biocompatible, flexible, and an elastic membrane-forming polymer.").

Claim 8 [8C] (cont'd): the first major surface of the layer being adapted to be placed adjacent to the damaged tissue,

Where Found in the Prior References:

Schwartz '823: Abstract ("The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen."); Figs. 6-9, 13, 15; col. 2:37-40 ("In essence, this improvement makes it possible to provide a stent able to support body lumens and conform to curves or irregularities in body lumens."); col. 2:44-54 ("The composite stent of the present invention can be delivered to the site of the occlusion by catheter and expanded conventionally, causing the film to expand or open radially along with the metallic elements of the stent and to be brought into contact with the body lumen. The polymeric film is flexible and preferably an elastic or stretchable film that is capable of conforming to the movement of the metallic stent elements when expanded into contact with a body lumen."); col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:48-54; col. 3:58-col. 4:6; col. 6:49-52 ("As shown in Fig. 13, the stent can be delivered to the body lumen and expanded (e.g. by use of a balloon catheter) into contact with the body lumen."); col. 6:33-37 ("As shown in Fig. 9, with the angioplasty procedure completed, balloon is deflated and withdrawn leaving stent firmly implanted within vessel with the film held in contact with the vessel."); col. 6:62-68 ("Once in the desired location, the stent can be released from the catheter and expanded into contact with the lumen as shown in Fig. 15 where it can conform to the curvature of the body lumen. The flexible film is able to form folds which allow the stent elements to readily adapt to the curvature of the body lumen.").

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14 ("The present invention satisfies this need by providing a separate sleeve to encompass the stent and serve as a local drug delivery device to

prevent thrombosis."); col. 4:53-55 ("The present invention satisfies this need by providing a separate sleeve to encompass a stent to locally administer drugs to prevent restenosis."); col. 4:58-68 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. . . . Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 5:26-29; col. 6:49-55 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface); col. 8:8-22; col. 8:58-60 ("The films were placed to line the circumference of a 2 cm length of ePTFE grafts, over which a 2 cm long stent was deployed."); col. 9:12-16 ("In addition, polymer-drug films which prevent thrombosis in the baboon and pig AV shunt system can be studied following stent-film placement in carotid, superficial femoral and coronary arteries following balloon injury of those vessels."); col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Fig. 8; col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:12-20 ("Stents are typically implanted within a vessel in a contracted state and expanded when in place in the vessel in order to maintain patency of the vessel to allow fluid flow through the vessel. Ideally, the implantation of such stents is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:50-56

("The stent can be used in coronary arteries or any other part of the vasculature or other body lumen where mechanical opening force is necessary or desirable to keep the vessel open or to maintain the stent flush against the lumen wall, and where an anti-restenosis, anti-proliferative or other types of therapeutic drug or agent is to be simultaneously positioned and diffused."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 2:23-33; col. 5:15-17; col. 7:56-62; col. 9:63-67 ("The deployment of the stent can also be improved by . . . decreasing friction between the vessel or lumen wall and the stent."); col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:52-54 ("The invention provides prostheses which may be inserted into a lumen of a body and fixed to the lumen wall adjacent an area needing treatment."); col. 1:63-66 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery."); col. 2:7-9 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:25-27 ("The current invention contemplates the usage of any prosthesis which elutes drugs locally to treat a lumen in need of repair."); col. 6:36-38; col. 6:56-58 ("The stent shown in Figs. 2 and 4 is a metallic malleable design which may be forced against a lumen wall by a balloon catheter which fixes it into position."); col. 6:64-67 ("The variations of design shown in the embodiments of Figs. 1 and 2 show that the prosthesis of the invention must be secured against a lumen wall and must carry a drug-eluting polymer."); col. 9:67-10:3 ("By including a metal stent within the lumen of the polymeric prosthesis, the polymeric prosthesis is effectively held against the wall of the body lumen by the strength of the metal stent."); col. 10:23-38 ("The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen. This will bring the bioabsorbable element into supporting contact with a body lumen at an interior position of the body lumen to be treated and will position the bioabsorbable element to deliver drugs to the body lumen. Following the expansion of the stents into luminal contact, the balloon (if the expansion device is a balloon) can be deflated which allows the luminal flow to be restored."); col. 10:46-59; col. 11:10-13; col. 11:17-20; col. 11:50-53 ((b) a body including a plurality of support elements forming an open-ended, radially expandable, self-supporting tubular structuring having an interior surface and an exterior surface."); col. 12:1-15.

Berg '354: Page 2:14-18 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen. Examples of stents which have been successfully applied over a PTCA balloon and radially expanded at the same time as the balloon expansion of an affected

artery include the stents disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) which are incorporated herein by reference in their entirety."); p. 2:34-36 ("Metal stents such as those disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) could be suitable for drug delivery in that they are capable of maintaining intimate contact between a substance applied to the outer surface of the stent and the tissues of the vessel to be treated."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:16-18 ("In operation, the stent made according to the present invention can deliver drugs to a body lumen by introducing the stent transluminally into a selected portion of the body lumen and radially expanding the stent into contact with the body lumen.").

Buscemi '450: Col. 3:14-15 ("The stent strengthens an area of the vessel that is in contact with the stent."); col. 3:21-25 ("The tubular main body includes an outer surface and inner surface. The outer surface of the main body faces an inner surface wall of the vessel. The inner surface of the stent faces a stream flowing through the lumen as shown in cross section in Fig. 2."); col. 4:61-64 ("The stent is secured by releasing the stent from compression so that the stent can radially spring out to abut against the inner surface wall of the vessel."); col. 6:49-52; col. 7:27-29; col. 8:9-11.

Ding '536: Col. 5:38-40 ("Surface material should minimize tissue rejection and tissue inflammation and permit encapsulation by tissue adjacent the stent implantation site.").

Dinh '227: Col. 1:32-35 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing mechanical support for the lumen."); col. 8:20-23 ("The term "stent" herein means any device which when placed into contact with a site in the wall of a lumen to be treated, will also place fibrin at the lumen wall and retain it at the lumen wall."); col. 8:37-43; col. 9:18-24 ("The stent is then delivered through the body lumen on the catheter to the treatment site where the stent is released from the catheter to allow it to expand into contact with the lumen wall.").

Domb '055: Abstract ("Preferred embodiments include catheters, tubes, and implants that abut tissue following implantation into the body . . ."); col. 4:25-32; col. 5:27-33; col. 5:49-54; col. 5:63-6:1 ("Coating that part of the tube, which is in contact with the mucosa, with the drug-loaded polymer provides a sustained release of steroids and antibiotics locally and at high concentration in the area which is critically affected, achieving the same effect as the systemic administration of the drugs without their side effects, throughout the duration of the intubation."); col. 6:8-18; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages.").

Kowligi '782: Abstract; col. 1:18-41; Figs. 2, 3; col. 10:18-67.

Hunter '981: Col. 4:24-38; col. 5:1-6; col. 16:31-56; col. 22:3-7; col. 22:54-58; col. 23:6-13 ("[M]ethods are provided for expanding the lumen of a body passageway, comprising inserting a stent into the passageway, the stent having a generally tubular structure, the surface of the structure being coated with an anti-angiogenic composition . . . such that the passageway is expanded."); col. 23:30-31; col. 23:46-51; col. 24:45-51; col. 24:66-25:5; col. 25:24-29; col. 25:48-54; col. 52:4-8 ("This film is designed to be placed on exposed tissue so that any encapsulated drug is released from the polymer over a long period of time at the tissue site."); 86:56-59; col. 87:11-22; col. 88:19-26.

Lambert '922: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion."); col. 3:54-61; col. 8:1-6.

Lambert '308: Page 3:24-27 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion.").

Myler '563: Col. 3:34-37 ("Stent 10 is illustrated in its expanded position at a treatment location adjacent vascular wall in an artery, in accordance with one aspect of the present invention."); col. 4:53-56 ("The exterior surface of the envelope which will contact the arterial wall is optionally made porous to enable the release of drugs from the envelope and/or stent to the treatment site."); col. 10:12-14 ("The balloon is inflated, thereby expanding the stent radially outwardly until it contacts either a previously dilated, or presently stenosed wall."); col. 10:56-61; col. 11:63-65 ("Once the stent has been positioned at the treatment site, axial elongating tension is released, and it is permitted to radially expand against the lumen wall."); col. 13:15-17 ("The exterior coating which will contact the arterial wall is optionally made porous to enable the release of drugs to the treatment site.").

Palmaz '417: col. 4:25-37 (" . . . expanding a portion of the catheter associated with the prostheses to force at least one of the prostheses radially outward into contact with the body passageway . . .").

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); Figs. 1 and 2; col. 9:18-10:3.

Strecker '746: Figs. 7 & 8.

Schiraldi '243: Col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Valentini '029: Abstract ("In particular, tubular channels which have a smooth inner surface and longitudinally oriented trabeculae result in significantly larger regenerated nerve cables and higher numbers of regenerated myelinated axons."); Figure 3; col. 2:32-35 ("Medical devices employing such selectively permeable materials, particularly semipermeable tubular devices having smooth inner skins, are disclosed for use in regenerating nerves."); col. 2:58-3:14; col. 5:33-41; col. 6:14-24.

Bawa '279: Col. 6:40-44; col. 12:29-34.

Wood '066: Col. 2:67-3:32 ("The object of this invention is to provide means for delivery effective dosages of therapeutic agents to sites of trauma such as wounds, thermal or chemical burns, ulcers, lesions, or surgical sites.").

Aebischer '486: Fig. 1.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:63-2:2; col. 2:21-32; col. 2:33-38; col. 2:39-46; col. 3:63-4:31 ("It can be of advantage for the lining to be of several layers, each impregnated with different medications. . . . It has also been demonstrated practical for the inner layer of the lining to be impregnated with antithrombotics and the outer with antiproliferatives and/or other medicational substances."); Fig. 4; col. 5:18-20 ("Fig. 4 is a view similar to that of Fig. 2 of an endoprosthesis with a multiple-layer lining and with its ends coated with medication."); col. 5:34-41 ("The endoprosthesis . . . is completely enclosed in an inner lining component and an outer lining component."); Fig. 7; col. 6:30-44 ("The endoprosthesis 40 in the embodiment illustrated in Fig. 7 comprises a lining 42 and 43 in the form of a double walled sleeve. The outer lining component 43 of the in-place and expanded stent rests against the inner surface 46 of the blood vessel. Inner lining component 42 rests against the stent."); col. 7:16-35; col. 7:48-65; col. 8:19-10:19.

Lambert '246: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion.").

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Bellamkonda '029: Fig. 6.

Dayton '382: Abstract ("The stent is then coated with a polymer or is formed from a polymer which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids . . ."); col. 4:4-10; col. 6:64-7:7; col. 8:18-19 ("a polymer forming the exterior surface of said stent for operative contact with said tissue . . .").

Burt '036: p.14:9-27; p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size.").

Goldin '568: Figs. 5A-5F; col. 9:7-12 (" . . . a substance that, when implanted in or juxtaposed against a living body . . ."); col. 22:46-23:3.

Palmaz '665: Col.3: 55-65 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into the body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded..."); col. 5:9-13; Figure 4; col. 8:9-14.

Palmaz '762: Col. 4: 14-19 (...expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway..."); col. 4: 53-56; col. 5: 43-45; col. 9: 1-6.

Palmaz '337: Col. 3:60-4:2 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into a body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded, whereby the intraluminal graft prevents the body passageway from collapsing and decreasing the size of the expanded lumen."); col. 4: 36-40; col. 5: 32-34; col. 7: 28-36; col. 8: 17-22.

Zaffaroni '254: Col. 7: 18-25 ("Secondly, the carrier contacts and bathes the inner surface of wall 11 for facilitating drug transfer from the carrier to the wall so that drug molecules can dissolve in a diffusive medium in the microporous wall and migrate through it to the outer surface thereof.").

Aebischer: Fig. 2A (disclosing one major surface facing the nerve stumps).

Dev: Abstract ("Polymer-coated stents could be used for local drug delivery to the vessel wall."); p. 273 (" . . . to compare these two drugs with respect to kinetics of their delivery to the arterial wall with the stent in place . . .").

Claim 8 [8D] (cont'd): the second major surface of the layer being adapted to be placed opposite to the damaged tissue,

Where Found in the Prior References:

Schwartz '823: Abstract ("The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen."); Figs. 6-9, 13, 15; col. 2:37-40 ("In essence, this improvement makes it possible to provide a stent able to support body lumens and conform to curves or irregularities in body lumens."); col. 2:44-54 ("The composite stent of the present invention can be delivered to the site of the occlusion by catheter and expanded conventionally, causing the film to expand or open radially along with the metallic elements of the stent and to be brought into contact with the body lumen. The polymeric film is flexible and preferably an elastic or stretchable film that is capable of conforming to the movement of the metallic stent elements when expanded into contact with a body lumen."); col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:48-54; col. 3:58-col. 4:6; col. 6:49-52 ("As shown in Fig. 13, the stent can be delivered to the body lumen and expanded (e.g. by use of a balloon catheter) into contact with the body lumen."); col. 6:33-37 ("As shown in Fig. 9, with the angioplasty procedure completed, balloon is deflated and withdrawn leaving stent firmly implanted within vessel with the film held in contact with the vessel."); col. 6:62-68 ("Once in the desired location, the stent can be released from the catheter and expanded into contact with the lumen as shown in Fig. 15 where it can conform to the curvature of the body lumen. The flexible film is able to form folds which allow the stent elements to readily adapt to the curvature of the body lumen.").

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14 ("The present invention satisfies this need by providing a separate sleeve to encompass the stent and serve as a local drug delivery device to prevent thrombosis."); col. 4:53-55 ("The present invention satisfies this need by providing a separate sleeve to encompass a stent to locally administer drugs to prevent restenosis."); col. 4:58-68 ("This invention provides a sheath for encompassing at least a portion of a stent to

locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. . . . Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 5:26-29; col. 6:49-55 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface); col. 8:8-22; col. 8:58-60 ("The films were placed to line the circumference of a 2 cm length of ePTFE grafts, over which a 2 cm long stent was deployed."); col. 9:12-16 ("In addition, polymer-drug films which prevent thrombosis in the baboon and pig AV shunt system can be studied following stent-film placement in carotid, superficial femoral and coronary arteries following balloon injury of those vessels."); col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:12-20 ("Stents are typically implanted within a vessel in a contracted state and expanded when in place in the vessel in order to maintain patency of the vessel to allow fluid flow through the vessel. Ideally, the implantation of such stents is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:50-56 ("The stent can be used in coronary arteries or any other part of the vasculature or other body lumen where mechanical opening force is necessary or desirable to keep the vessel open or to maintain the stent flush against the lumen wall, and where an anti-restenosis, anti-proliferative or

other types of therapeutic drug or agent is to be simultaneously positioned and diffused."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 2:23-33; col. 5:15-17; col. 7:56-62; col. 9:63-67 ("The deployment of the stent can also be improved by . . . decreasing friction between the vessel or lumen wall and the stent."); col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:52-54 ("The invention provides prostheses which may be inserted into a lumen of a body and fixed to the lumen wall adjacent an area needing treatment."); col. 1:63-66 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery."); col. 2:7-9 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:25-27 ("The current invention contemplates the usage of any prosthesis which elutes drugs locally to treat a lumen in need of repair."); col. 6:36-38; col. 6:56-58 ("The stent shown in Figs. 2 and 4 is a metallic malleable design which may be forced against a lumen wall by a balloon catheter which fixes it into position."); col. 6:64-67 ("The variations of design shown in the embodiments of Figs. 1 and 2 show that the prosthesis of the invention must be secured against a lumen wall and must carry a drug-eluting polymer."); col. 9:67-10:3 ("By including a metal stent within the lumen of the polymeric prosthesis, the polymeric prosthesis is effectively held against the wall of the body lumen by the strength of the metal stent."); col. 10:23-38 ("The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen. This will bring the bioabsorbable element into supporting contact with a body lumen at an interior position of the body lumen to be treated and will position the bioabsorbable element to deliver drugs to the body lumen. Following the expansion of the stents into luminal contact, the balloon (if the expansion device is a balloon) can be deflated which allows the luminal flow to be restored."); col. 10:46-59; col. 11:10-13; col. 11:17-20; col. 11:50-53 ((b) a body including a plurality of support elements forming an open-ended, radially expandable, self-supporting tubular structuring having an interior surface and an exterior surface."); col. 12:1-15.

Berg '354: Page 2:14-18 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen. Examples of stents which have been successfully applied over a PTCA balloon and radially expanded at the same time as the balloon expansion of an affected artery include the stents disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) which are incorporated herein by reference in their entirety."); p. 2:34-36 ("Metal stents such as those disclosed in US-A-4733665 (Palmaz), US-A-4800882

(Gianturco) and US-A-4886062 (Wiktor) could be suitable for drug delivery in that they are capable of maintaining intimate contact between a substance applied to the outer surface of the stent and the tissues of the vessel to be treated."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:16-18 ("In operation, the stent made according to the present invention can deliver drugs to a body lumen by introducing the stent transluminally into a selected portion of the body lumen and radially expanding the stent into contact with the body lumen.").

Buscemi '450: Col. 3:14-15 ("The stent strengthens an area of the vessel that is in contact with the stent."); col. 3:21-25 ("The tubular main body includes an outer surface and inner surface. The outer surface of the main body faces an inner surface wall of the vessel. The inner surface of the stent faces a stream flowing through the lumen as shown in cross section in Fig. 2."); col. 4:61-64 ("The stent is secured by releasing the stent from compression so that the stent can radially spring out to abut against the inner surface wall of the vessel."); col. 6:49-52; col. 7:27-29; col. 8:9-11.

Ding '536: Col. 5:38-40 ("Surface material should minimize tissue rejection and tissue inflammation and permit encapsulation by tissue adjacent the stent implantation site.").

Dinh '227: Col. 1:32-35 ("The stent is typically inserted by catheter into a vascular lumen told [sic] expanded into contact with the diseased portion of the arterial wall, thereby providing mechanical support for the lumen."); col. 8:20-23 ("The term "stent" herein means any device which when placed into contact with a site in the wall of a lumen to be treated, will also place fibrin at the lumen wall and retain it at the lumen wall."); col. 8:37-43; col. 9:18-24 ("The stent is then delivered through the body lumen on the catheter to the treatment site where the stent is released from the catheter to allow it to expand into contact with the lumen wall.").

Domb '055: Abstract ("Preferred embodiments include catheters, tubes, and implants that abut tissue following implantation into the body . . ."); col. 4:25-32; col. 5:27-33; col. 5:49-54; col. 5:63-6:1 ("Coating that part of the tube, which is in contact with the mucosa, with the drug-loaded polymer provides a sustained release of steroids and antibiotics locally and at high concentration in the area which is critically affected, achieving the same effect as the systemic administration of the drugs without their side effects, throughout the duration of the intubation."); col. 6:8-18; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be

instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages.").

Kowligi '782: Abstract; col. 1:18-41; Figs. 2, 3; col. 10:18-67.

Hunter '981: Col. 4:24-38; col. 5:1-6; col. 16:31-56; col. 22:3-7; col. 22:54-58; col. 23:6-13 ("[M]ethods are provided for expanding the lumen of a body passageway, comprising inserting a stent into the passageway, the stent having a generally tubular structure, the surface of the structure being coated with an anti-angiogenic composition . . . such that the passageway is expanded."); col. 23:30-31; col. 23:46-51; col. 24:45-51; col. 24:66-25:5; col. 25:24-29; col. 25:48-54; col. 52:4-8 ("This film is designed to be placed on exposed tissue so that any encapsulated drug is released from the polymer over a long period of time at the tissue site."); 86:56-59; col. 87:11-22; col. 88:19-26.

Lambert '922: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion."); col. 3:54-61; col. 8:1-6.

Lambert '308: Page 3:24-27 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion.").

Myler '563: Col. 3:34-37 ("Stent 10 is illustrated in its expanded position at a treatment location adjacent vascular wall in an artery, in accordance with one aspect of the present invention."); col. 4:53-56 ("The exterior surface of the envelope which will contact the arterial wall is optionally made porous to enable the release of drugs from the envelope and/or stent to the treatment site."); col. 10:12-14 ("The balloon is inflated, thereby expanding the stent radially outwardly until it contacts either a previously dilated, or presently stenosed wall."); col. 10:56-61; col. 11:63-65 ("Once the stent has been positioned at the treatment site, axial elongating tension is released, and it is permitted to radially expand against the lumen wall."); col. 13:15-17 ("The exterior coating which will contact the arterial wall is optionally made porous to enable the release of drugs to the treatment site.").

Palmaz '417: col. 4:25-37 (" . . . expanding a portion of the catheter associated with the prostheses to force at least one of the prostheses radially outward into contact with the body passageway . . .").

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); Figs. 1 and 2; col. 9:18-10:3.

Strecker '746: Figs. 7 & 8.

Schiraldi '243: Col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier

membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Valentini '029: Abstract ("In particular, tubular channels which have a smooth inner surface and longitudinally oriented trabeculae result in significantly larger regenerated nerve cables and higher numbers of regenerated myelinated axons."); Figure 3; col. 2:32-35 ("Medical devices employing such selectively permeable materials, particularly semipermeable tubular devices having smooth inner skins, are disclosed for use in regenerating nerves."); col. 2:58-3:14; col. 5:33-41; col. 6:14-24.

Bawa '279: Col. 6:40-44; col. 12:29-34.

Wood '066: Col. 2:67-3:32 ("The object of this invention is to provide means for delivery effective dosages of therapeutic agents to sites of trauma such as wounds, thermal or chemical burns, ulcers, lesions, or surgical sites.").

Aebischer '486: Fig. 1.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:63-2:2; col. 2:21-32; col. 2:33-38; col. 2:39-46; col. 3:63-4:31 ("It can be of advantage for the lining to be of several layers, each impregnated with different medications. . . . It has also been demonstrated practical for the inner layer of the lining to be impregnated with antithrombotics and the outer with antiproliferatives and/or other medicational substances."); Fig. 4; col. 5:18-20 ("Fig. 4 is a view similar to that of Fig. 2 of an endoprosthesis with a multiple-layer lining and with its ends coated with medication,"); col. 5:34-41 ("The endoprosthesis . . . is completely enclosed in an inner lining component and an outer lining component."); Fig. 7; col. 6:30-44 ("The endoprosthesis 40 in the embodiment illustrated in Fig. 7 comprises a lining 42 and 43 in the form of a double walled sleeve. The outer lining component 43 of the in-place and expanded stent rests against the inner surface 46 of the blood vessel. Inner lining component 42 rests against the stent."); col. 7:16-35; col. 7:48-65; col. 8:19-10:19.

Lambert '246: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion.").

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Dayton '382: Abstract ("The stent is then coated with a polymer or is formed from a polymer which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids . . ."); col. 4:4-10; col. 6:64-7:7; col. 8:18-19 ("a polymer forming the exterior surface of said stent for operative contact with said tissue . . .").

Burt '036: p.14:9-27; p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size.").

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Palmaz '762: Col. 4: 14-19 (...expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway..."); col. 4: 53-56; col. 5: 43-45; col. 9: 1-6.

Palmaz '337: Col. 3:60-4:2 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into a body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded, whereby the intraluminal graft prevents the body passageway from collapsing and decreasing the size of the expanded lumen."); col. 4: 36-40; col. 5: 32-34; col. 7: 28-36; col. 8: 17-22.

Zaffaroni '254: Col. 7: 18-25 ("Secondly, the carrier contacts and bathes the inner surface of wall 11 for facilitating drug transfer from the carrier to the wall so that drug molecules can dissolve in a diffusive medium in the microporous wall and migrate through it to the outer surface thereof.").

Aebischer: Fig. 2A (disclosing one major surface facing the nerve stumps).

Dev: Abstract ("Polymer-coated stents could be used for local drug delivery to the vessel wall."); p. 273 (" . . . to compare these two drugs with respect to kinetics of their delivery to the arterial wall with the stent in place . . .").

Claim 8 [8E] (cont'd): the layer having material release means for release of an at least one treating material in a unidirectional manner when said layer is placed adjacent to the damaged tissue,

Where Found in the Prior References:

Peterson '166: Abstract ("A time-release chemical delivery system in which a bioactive compound is attached to a polymeric biodegradable carrier by a hydrolysable bond is disclosed. The bioactive compound can either be bound directly to the polymer or be attached to the polymer via a spacer group."); col. 1:28-38; col. 1:51-55 ("Another object of the instant invention is to provide a bioactive compound via covalent bonding to a polymeric backbone so that upon hydrolysis of said covalent bond said bioactive compound is released in active, unmodified form."); col. 1:60-62; col. 1:67-col. 2:2; col. 2:40-50 ("A further requirement of the polymeric carriers are that they contain a pendant group to which a reactive compound may be directly attached by a hydrolyzable bond or to which a spacer unit may be attached with the reactive compound attached to the spacer unit by a hydrolysable bond. Typically, the space [sic] unit will also be attached to the polymeric carrier by a hydrolyzable bond."); col. 2:51-60; col. 3:67-4:2; col. 4:3-7 ("The use of a spacer group may also provide desirable changes in drug release rate by allowing ease of hydrolysis of the drug."); col. 4:8-19; col. 4:56-5:2; col. 6:28-55; col. 6:55-62 ("Since the proximity of the reactive carboxyl group to the polymer backbone may interfere with the addition of a bioactive compound, especially a large molecule, and with the subsequent hydrolysis of a covalent bond formed by such condensation reaction, the use of a spacer group, preferably linear in nature, may be preferred in this invention."); col. 6:65-col.7:28 ("To be effective as hydrolysable carriers the polymers of this invention must have pendant reactive sites to which a bioactive compound may be attached. . . . These functional groups may react with functional groups of the bioactive compound to form a hydrolysable bond. The hydrolysable bond may be direct between the pendant group of the polymer and the reactive compound or it may be first reacted with a spacer unit which contains a similar reactive functional group. . . . The reactivity of the reactive sites is also affected by the distance of the reactive site from the backbone of the polymer."); col. 7:32-53 ("Spacer groups may be utilized in the practice of the instant invention to provide a hydrolysable unit which spaces the reactive compound further from the carrier backbone. As indicated hereinabove, the polymeric units may contain long pendant chains which place the reactive site on the pendant group further away from the carrier backbone. . . ."); col. 7:57-62 ("Bioactive compounds useful in this invention are those which contain a group which may react to form a bond with a pendant group or a spacer group. The bond is preferably hydrolysable and in particular are esters, including sulfates or phosphate esters, amides, carbonates and urethane bonds."); col.8:25-28 ("The reactive compound which is released over a period of time in the instant invention may be one which has a pharmacological affect upon the host, for example, a contraceptive drug in an animal."); col. 8:34-49 ("Factors which affect the release rate and the rate of absorption into the body of the host include . . . the composition of the polymer backbone, the length and character of the spacer groups and the character of the pendant groups The spacing of the bulky drug or chemically

reacted compound from the polymer also affects the rate of release."); col. 11:25-12:4 ("... a bioactive compound chemically attached to said carrier by a hydrolysable bond, said bioactive compound containing a group which reacts with a group on the biodegradable polymer to form a hydrolysable bond and being effective in small dosages to produce a biological effect within said host upon release into the host by hydrolysis of the hydrolyzable bond."); col. 12:14-24 ("The chemical delivery system of claim 1 wherein said bioactive compound is indirectly coupled to said carrier by a hydrolyzable bond to a spacer compound. . . . The chemical delivery system of claim 7 wherein said spacer compound is coupled to said bioactive compound by a hydrolyzable bond."); col. 12:28-30.

Schwartz '823: Col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:64-4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof."); col. 7:1-4 ("In yet another aspect of the present invention, various therapeutic substances can be incorporated in or applied to the polymeric film to provide such substances to the blood or to the lumen wall."); col. 7:14-25 ("Application of the therapeutic substance to the film can include applying it on the surface of the film or incorporating it into the film as it is made. For example, microcapsules can be used to carry the therapeutic substance either in or on the film and to provide timed-release of the substance to the blood, or to the blood vessel or both."); col. 7:25-34 ("Microcapsules containing one type of therapeutic substance could be provided on one side of the film and microcapsules containing another therapeutic substance could be incorporated on the other side of the film, thus providing a stent according to the present invention which provides one type of therapeutic substance (e.g. an anti-thrombotic drug) to the blood and another type of therapeutic substance (e.g. an antiproliferative drug) to the vessel wall."); col.8:5-11 ("The resulting stent has microcapsules containing one therapeutic substance on the inside (and able to contact blood once implanted in a blood vessel) and microcapsules containing a second therapeutic substance on the outside (and able to contact the vessel wall when implanted in contact with the vessel wall)."); col. 8:46-47.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14; col. 4:53-55; col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent.

The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-33; col. 5:34-6:23 ("Many polymers can also be used to make the sheath, including biodegradable and non-degradable polymers. The polymer is selected depending on the drug selected, the polymer's compatibility with a subject and the ultimate pharmacologic effect desired. . . . Another alternative would be to use a polymer which is biodegradable over a short period of time. Naturally, the opposite characteristics would be selected for a desired prolonged release. The characteristics of the particular polymer for these purposes is well known to the skilled artisans or can be determined by reference to standard references . . ."); col. 6:39-41 ("The initial prototype is a sleeve of polymer, either degradable or non-degradable, that covers the entire stent (Fig. 3)"); col. 6:64-68 ("The duration of drug delivery is accurately predicted by the characteristics of the polymer. For example, if the polymer is biodegradable, then the rate and duration of drug delivery is related to the thickness of the polymer."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface."); col. 8:23-54; col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33 ("In combination, a hollow tubular stent having a predetermined length and a separate sheath removably encompassing at least a portion of said hollow tubular stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug."); col. 11:11-12 ("14. The sheath of claim 1, wherein the polymer is biodegradable."); col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in

opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 5:4-9 ("The primary function of the sheet of polymeric material is to deliver therapeutic agents or drugs to help prevent thrombosis and/or restenosis."); col. 5:49-6:25 ("The polymeric material is preferably bioabsorbable, and is preferably loaded or coated with a therapeutic agent or drug . . ."); col. 7:23-25; col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:63-2:6 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery. The prostheses may be completely biodegradable or may be bioabsorbable in whole or incorporated into the lumen wall as a result of tissue overgrowth, i.e. endothelialization. Alternatively, the prostheses may be biostable in which case the drug is diffused out from the biostable materials in which it is incorporated."); col. 2:28-30 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 2:55-58; Fig. 5; col. 6:5-10 ("When drugs are delivered locally via the prosthesis of the invention, they may be at therapeutic levels at the diseased site while at the lower limits of detectability in the bloodstream. So little drug is required for effective local treatment of a lumen that the drug may not be detectable in blood samples."); col. 6:36-38; col. 6:59-63 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously. the polymer may be biostable or bioabsorbable. If biostable, the drug would diffuse out of the polymer."); col. 6:64-67; col. 7:19-23; col. 7:53-55 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 7:59-8:25; col. 8:26-31 ("The compound which is preferred is a polyphosphate ester. Polyphosphate ester is a compound such as that disclosed in U.S. Pat. Nos. 5,176,907; 5,194,581; and 5,656,765 issued to Leong which are incorporated herein by reference. Similar to polyanhydrides, polyphosphate ester is being researched for the sole purpose of drug delivery."); col. 8:40-9:22 ("It is the hydrolytic instability of the phosphorous ester bond which makes this polymer attractive for controlled drug release applications. A wide range of controllable degradation rates can be obtained by adjusting the hydrophobicities of the backbones of the backbones of the polymers and yet assure biodegradability. The functional side groups allow for the chemical linkage of drug molecules to the polymer."); col. 12:12-15.

Berg '354: Page 2:27-31 ("Other methods of providing therapeutic substances to the vascular wall include simple heparin-coated metallic stents, whereby a heparin coating is ionically or covalently bonded to the stent. Still other methods of providing therapeutic substances to the vascular wall by means of stents have also been proposed such as in US-A-5102417 (Palmaz), WO-91/12779 "Intraluminal Drug Eluting Prosthesis" and WO-90/133332

"Stent With Sustained Drug Delivery".); p. 3:7-9; p. 3:22-23 ("It also provides a drug-containing stent which allows for a sustained release of the drug to vascular tissue."); p. 4:25-27 ("The ratio of therapeutic substance to polymer in the solution will depend on the efficacy of the polymer in securing the therapeutic substance onto the stent and the rate at which the coating is to release the therapeutic substance to the tissue of the blood vessel."); p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Abstract ("A stent made of biodegradable material includes a drug that is released at a rate controlled by the rate of degradation of the biodegradable material."); col. 1:61-63; col. 2:6-8 ("The mechanism of biodegradation is described as hydrolysis resulting in degradable products excreted in urine or reabsorbed into tissues."); col. 2:49-52 ("Also desired are stents which can deliver drugs or biologically active agents at a controlled rate to blood passing through the vessel lumen as well as to the vessel wall."); col. 2:56-61 ("The biodegradable stent is made from at least one biodegradable material that is also biocompatible and includes a drug which is released into the lumen of the vessel at a rate controlled by the rate of degradation of the biodegradable material."); col. 3:11-12 ("The rate of drug release is controlled by the rate of degradation of the biodegradable materials."); col. 3:53-55; col. 4:12-14; col. 4:23-25 ("The present invention further includes a main body having more than one biodegradable interior film layer."); col. 4:65-5:5 "In the most preferred embodiment, the biodegradable stent of the present invention is made of biodegradable materials that are also biocompatible. By biodegradable is meant that a material will undergo breakdown or decomposition into harmless compounds as part of a normal biological process"); col. 5:11-19 ("Suitable biodegradable materials for the main body of the stent of the present invention include polylactic acid, polyglycolic acid (PGA), collagen or other connective proteins or natural materials, polycaprolactone, hyaluric acid, adhesive proteins, co-polymers of these materials as well as composites and combinations thereof and combinations of other biodegradable polymers."); col. 5:21-37; col. 5:38-45 ("Consequently, the presence of different biodegradable materials in the stent permits the stent to degrade in a predictable, orchestrated fashion."); col. 5:46-54 ("As the stent biodegrades, drugs are administered to the surrounding tissue or to the blood stream. Thus, the rate of drug release is controlled by the rate of degradation of the biodegradable materials."); col. 6:3-8; col. 6:45-59; col. 7:2-9; col. 7:32-8:9; col. 8:27-30.

Ding '536: Abstract ("In one embodiment, the surface is provided with sites of high electronegativity species by coating with fluorosilicone which aid in controlled elution, particularly the initial release rate, and reduce thrombogenic activity."); col. 2:38-42 ("Such an approach is described by Winters, et al., in U.S. Pat. Nos. 5,182,317; 5,262,451 and 5,338,770 in which the amine functional groups of the active material are covalently bonded using a polyethylene oxide (PEO) on a siloxane surface."); col. 2:43-46 ("Another approach is described in U.S. Pat. No. 4,613,665 to Larm in which heparin is chemically covalently bound to impart a non-thrombogenic surface to the material."); col. 3:19-27 ("Accordingly, it is a primary object of the present invention to provide a coating and process for coating a stent to be used as a deployed stent prosthesis, the coating being capable of effective controlled long-term delivery of biologically active materials. Another object of the invention is to provide a coating and process for coating a stent prostheses using a biostable hydrophobic elastomer in which biologically

active species are incorporated within a coating."); col. 6:16-27 ("The mechanism of incorporation of the biologically active species into the surface coating and egress mechanism depend both on the nature of the surface coating polymer and the material to be incorporated. The mechanism of release also depends on the mode of incorporation. The material may elute via interparticle paths or be administered via transport or diffusion through the encapsulating material itself."); col. 6:28-34; col. 6:35-48; col. 10:35-40 ("In addition, because of the negative charges on the heparin itself, the electro-negativity of the fluorosilicone topcoat may be, at least in part, responsible for the modified heparin release kinetic profile."); col. 12:62-67 ("Whereas the polymer of the coating may be any biostable elastomeric material capable of being adhered to the stent material as a thin layer, hydrophobic materials are preferred because it has been found that the release of the biologically active species can generally be more predictably controlled with such materials. Preferred materials include silicone rubber elastomers and biostable polyurethanes specifically.").

Dinh '227: Col. 2:26-32; col. 3:10-14; col. 5:53-55 ("Suitable polymers could also be biodegradable polymers such as polyphosphate ester, polyhydroxybutyrate valerate, polyhydroxybutyrate-co-hydroxyvalerate and the like."); col. 6:13-22; col. 6:32-50; col. 6:50-56; col. 7:10-13 ("The adhesion of the coating and the rate at which the drug is delivered can be controlled by the selection of an appropriate bioabsorbable or biostable polymer and by the ratio of drug to polymer in the solution."); col. 7:13-23; col. 7:30-44; col. 7:45-51 ("The polymer used can be bioabsorbable or biostable polymer. Suitable bioabsorbable polymers include poly(L-lactic acid), poly(lactide-co-glycolide) and poly(hydroxybutyrate-co-valerate). Suitable biostable polymers include silicones, polyurethanes, polyesters, vinyl homopolymers and copolymers, acrylate homopolymers and copolymers, polyethers and cellulose."); col. 9:17-18; col. 12:38-50.

[Domb '055: Abstract ("Preferred polymeric coatings are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); col. 3:54-62 ("In the preferred embodiments, these have utilized bioerodible polymers as the matrix for the drug to be released, usually as a function of diffusion and erosion of the polymer. The advantage of these drug delivery systems is that they provide a sustained/continuous release of drugs locally and at a relatively high concentration in areas of the body, without systemic side-effects, throughout the duration of their release."); col. 4:11-13 ("It is a further object of the present invention to provide medical devices having prolonged low-dose, localized release of anti-microbial and anti-inflammatory agents."); col. 4:33-36; col. 5:27-33; col. 5:41-45 ("The drug-loaded polymer provides a sustained release of steroids and antibiotics locally and at a relatively high concentration in that area which is critically affected, without the side-effects of the systemic administration of the same drugs, throughout the duration of intubation."); col. 5:49-54; col. 5:60-6:1 ("An esophageal silicone stent coated with a film of polymer can be used to provide a site-specific controlled release of corticosteroids and antibiotics."); col. 6:3-7; col. 6:24-26 ("Examples of suitable polymers include ethylene vinyl acetate, polyurethane, silicones, hydrogels, polyurethane, and polyvinyl chloride."); col. 6:42-45 ("Release is a function of diffusion of the agent from the polymeric matrix, and varies by size, concentration and solubility of the agent, as well as by thickness and chemical composition of the polymeric matrix."); col. 7:10-20; col. 7:25-29; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having

exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 11:36-38 ("The medical device of claim 1, wherein the polymer is selected from the group consisting of polyurethane, ethylene vinyl acetate, silicones, hydrogels, and polyvinyl chloride."); col. 11:39-44; col. 12:1-7; col. 12:11-22; col. 12:23-25; col. 12:26-31; col. 12:32-42.

Fox '096: Abstract ("A method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers, and antimicrobial agents . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 3:55-67 ("The polymeric coating agent component of the coating vehicle of the present invention is selected from the group consisting of biomedical polyurethanes, biomedical silicones, biodegradable polymers and combinations thereof."); col. 4:30-5:35; col. 7:22-25; col. 7:28-32; col. 11:34-48 ("Suitable biodegradable polymers include the homopolymers poly(glycolic acid), poly(D-lactic acid), poly(D,L-lactic acid), poly(D,L-ethyl-glycolic acid), poly(dimethylglycolic acid), poly(D,L-methylethylglycolic acid), and poly(E-caprolactone), as well as biodegradable polyhydroxy butyric acid and mixtures thereof. A preferred biodegradable polymer is polylactic acid (PLA)."); col. 11:51-56 ("The biodegradable polymer modulates the rate of release of antimicrobial drugs."); Table IV; col. 12:24-41 ("Suitable biomedical poly(lactic) polymers include the poly(L-lactide), poly(D-lactide) and the poly (D-L-lactic acid). . . . The poly(lactic acid) polymers are bioerodible, and while they can be used alone, it is preferred that they be combined with either a biomedical polyurethane or a biomedical silicone."); col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages."); col. 18:19-25; col. 20:54-58; col. 28:13-18; col. 29:38-40 (Adding a biodegradable material containing anti-microbial agents to the adhesive to provide controlled-release through degradation."); col. 36:21-31; col. 36:47-51; col. 36:65-37:7; col. 37:29-31; col. 37:56-57; col. 37:63-65; col. 37:66-38:9; col. 38:24-30; col. 39:39-41; col. 40:33-34; col. 40:39-42.

Hunter '981: Abstract; col. 3:42-61 ("A wide variety of molecules may be utilized within the scope of the present invention as anti-angiogenic factors, including for example Anti-Invasive Factor, retinoic acids and their derivatives, paclitaxel including analogues and derivatives thereof, Suramin, Tissue Inhibitor of Metalloproteinase-1, Tissue Inhibitor-1 and Plasminogen Activator Inhibitor-2, and lighter "d group" transition metals. Similarly, a wide

variety of polymeric carriers may be utilized, representative examples of which include poly (ethylene-vinyl acetate) (40% cross-linked), poly (D,L-lactic acid) oligomers and polymers, poly (L-lactic acid) oligomers and polymers, poly(glycolic acid), copolymers of lactic acid and glycolic acid, poly(caprolactone), poly(valerolactone), poly(anhydrides), copolymers of poly(caprolactone) or poly(lactic acid) with polyethylene glycol, and blends thereof."); col. 5:27-32; col. 12:23-35 ("As noted above, the present invention provides compositions comprising an anti-angiogenic factor, and a polymeric carrier."); col. 16:31-56 ("[A]nti-angiogenic compositions of the present invention are provided in a wide variety of polymeric carriers, including for example both biodegradable and non-biodegradable compositions. Representative examples of biodegradable compositions include albumin, gelatin, starch, cellulose, dextrans, polysaccharides, fibrinogen, poly (D,L lactide), poly (D,L-lactide-co-glycolide), poly (glycolide), poly (hydroxybutyrate), poly (alkylcarbonate) and poly (orthoesters) Representative examples of nondegradable polymers include EVA copolymers, siliconerubber and poly (methylmethacrylate). Particularly preferred polymeric carriers include poly (ethylene-vinyl acetate)(40% cross-linked), poly(D,L-lactic acid) oligomers and polymers, poly (L-lactic acid) oligomers and polymers, poly (glycolic acid), copolymers of lactic acid and glycolic acid, poly (caprolactone), poly (valerolactone), polyanhydrides, copolymers of poly (caprolactone) or poly (lactic acid) with polyethylene glycol and blends thereof."); col. 16:31-56; col. 16:66-17:6 ("Anti-angiogenic factors may be linked by occlusion in the matrices of the polymer, bound by covalent linkages, or encapsulated in microcapsules. Within certain preferred embodiments of the invention, anti-angiogenic compositions are provided in non-capsular formulations such as microspheres . . . pastes, threads of various size, films and sprays."); col. 17:7-26; col. 17:41-43 ("Anti-angiogenic compositions may also be prepared, given the disclosure provided herein, for a variety of other applications."); col. 18:15-49 ("Within further aspects of the present invention, polymeric carriers are provided which are adapted to contain and release a hydrophobic compound, the carrier containing the hydrophobic compound in combination with a carbohydrate, protein or polypeptide. Within certain embodiments, the polymeric carrier contains or comprises regions, pockets, or granules of one or more hydrophobic compounds."); col. 47:58-49:7; col. 56:45-57; col. 57:17-31; col. 59:65-60:48; col. 59: 32-59 ("Poly(e-caprolactone) is an aliphatic polyester which can be degraded by hydrolysis under physiological conditions and it is non-toxic and tissue compatible."); col. 69:19-62; col. 77:43-55 ("The release of paclitaxel, in this case, is dominated by polymer degradation."); col. 78:58-79:5 ("Although not specifically set forth above, a wide variety of other polymeric carriers may be manufactured, including for example . . ."); col. 84:62-86:24; col. 86:60-67.

Kinsella '608: Col. 11:18-24 ("Drug delivery systems that can be valuable include drug-impregnated polymer-coated metallic stents [and] biodegradable drug-eluting polymer stents . . .").

Kowligi '782: Col. 4:16-27 ("In regard to elastomeric coating 38 shown in Fig. 2, such elastomeric coating is selected to be a biocompatible elastomers and may be selected from the group consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 10:18-27; col. 10:28-32 ("The implantable vascular graft recited by claim 1 wherein said elastomers is selected from the group of elastomers consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 10:43-50; col. 10:60-67.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 1:46-55 ("Release of heparin from intravascular catheters in quantities sufficient to decrease thrombosis on the catheter has been achieved by either covalently bonding a charged molecule to a polymer or incorporating a large nonmobile charged molecule on the surface of the polymer . . ."); col. 1:62-65; col. 2:16-35; col. 2:40-50 ("In accordance with the present invention, there is provided a method for preparing a system suitable for localized delivery of biologically active compounds to a subject."); col. 2:55-67; col. 3:8-12; col. 3:29-49; col. 4:10-17; col. 7:29-32; col. 7:38-41; col. 8:62-9:19 ("Adventitia overlying the stent contained 360 times the concentration of forskolin in the blood and 305 times the concentration of forskolin in the contralateral artery. . . . In a similar model, etretinate, a retinoic acid analog, develops concentrations in the media of 250 ng/mg tissue at 24 hours. At 24 hours, this concentration was over 2000 times the concentration in the blood."); col. 9:31-37 ("These data demonstrate that a polyurethane coated nitinol stent is capable of delivering a lipophilic drug in high local concentration in the vessel wall. The large 450 fold differential of local tissue levels of forskolin over blood levels reflects the capability of this delivery system to provide high local concentration and potentially higher efficacy, with lower risk of systemic side effects."); col. 12:21-22 ("The method in accordance with claim 1, wherein the biologically active compound is a lipophilic compound."); col. 12:27-30 ("The method in accordance with claim 1, wherein the biologically active compound is a hydrophilic compound, said method further comprising linking the hydrophilic compound to a lipophilic carrier.").

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p. 2:10-19 ("Release of heparin from intravascular catheters in quantities sufficient to decrease thrombosis on the catheter has been achieved by either covalently bonding a charged molecule to a polymer or incorporating a large nonmobile charged molecule on the surface of the polymer . . ."); p. 2:25-30; p. 3:10-31 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); p. 4:2-12; p. 4:17-31; p. 15:25-16:14 ("Adventitia overlying the stent contained 360 times the concentration of forskolin in the blood and 305 times the concentration of forskolin in the contralateral artery. . . . In a similar model, etretinate, a retinoic acid analog, develops concentrations in the media of 250 ng/mg tissue at 24 hours. At 24 hours, this concentration was over 2000 times the concentration in the blood."); p.16:27-34 ("These data demonstrate that a polyurethane coated nitinol stent is capable of delivering a lipophilic drug in high local concentration in the vessel wall. The large 450 fold differential of local tissue levels of forskolin over blood levels reflects the capability of this delivery system to provide high local concentration and potentially higher efficacy, with lower risk of systemic side effects."); claim 14 ("The method in accordance with claim 1, wherein the biologically active compound is a lipophilic compound."); claim 16 ("The method in accordance with claim 1, wherein the

biologically active compound is a hydrophilic compound, said method further comprising linking the hydrophilic compound to a lipophilic carrier."); claim 26.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8; p. 1:56-58.

Mitchell '711: Col. 6:24-28 ("Suitable solid carrier include, for example, calcium phosphate, magnesium stearate, talc, sugars, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, sodium carboxymethyl cellulose, polyvinylpyrrolidone, low melting waxes and ion exchange resins.").

Morris '781: Col. 10:50-54 ("Suitable solid carriers include, for example, calcium phosphate, magnesium stearate, talc, sugars, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, sodium carboxymethyl cellulose, polyvinylpyrrolidone, low melting waxes and ion exchange resins.").

Morris '182: Page 6:54-56 ("Suitable solid carriers include, for example, calcium phosphate, magnesium stearate, talc, sugars, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, sodium carboxymethyl cellulose, polyvinylpyrrolidone, low melting waxes and ion exchange resins.").

Myler '563: Col. 4:57-59; col. 4:60-67 ("[T]he stent can be provided with a solid drug carrier such as an impregnated porous solid wall or sponge for timed drug delivery."); col. 5:39-41 ("For the above reasons, even the expanded pores for drug delivery should be small enough to maximize or prevent cell penetration, but large enough for drug delivery."); col. 13:15-18 ("The exterior coating which will contact the arterial wall is optionally made porous to enable the release of drugs to the treatment site.").

Palmaz '417: Col. 11:8-11; col. 11:26-34 ("Examples of biologically compatible coatings would include coatings made of absorbable polymers such as those used to manufacture absorbable sutures. Such absorbable polymers include polyglycoides, polyacoides, and copolymers thereof. Such absorbable polymers could also contain various types of drugs, whereby as the coating is absorbed, or dissolves, the drug would be slowly released into the body passageway.").

Tice '330: Col. 3:20-33 ("A preferred group of polymeric wall forming materials includes those which are biodegradable such as aliphatic polyesters including polylactide, polyglycolide, polycaprolactone and copolymers thereof."); col. 8:38-51.

Thies '317: Abstract ("The capsules provide controlled release of the active agent over a prolonged period of time."); col.1:15-19 ("The art of encapsulation has developed various processes and methods for individually coating particular matter for purposes of controlled release or metering out of an active agent over a prolonged period."); col. 2:26-38; col. 2:43-47; col. 2: 48-51; col. 3:41-4:2; col. 6:35-39 ("Therefore, the presence of a soluble alkali metal silicate in the interior of the capsule causes much of the capsule coating material to simply

disappear upon immersion in water thereby causing accelerated release of the active agent."); col. 7:36-11:68; col. 12:10-40; col. 13:4-14:3.

Tice '840: Col. 2:32-34; col. 2:38-55 ("The polymeric matrix material of the microparticles of the present invention must be a biocompatible and biodegradable polymeric material. . . . Suitable examples of polymeric matrix materials include poly (glycolic acid), poly-d,l-lactic acid, copolymers thereof, copolyoxalates, polycaprolactone, poly (lactic acid-caprolactone), and the like."); col. 2:56-3:8 ("The molecular weight of a polymer is also important from the point of view that molecular weight influences the biodegradation rate of the polymer. The drug can also be released from the microparticles as the polymeric excipient bioerodes. By an appropriate selection of polymeric materials a microparticle formulation can be made such that the resulting microparticles exhibit both diffusional release and biodegradation release properties."); col. 10:56-11:15; col. 12:6-9.

Tice '025: Col. 2:32-34; col. 2:38-55 ("The polymeric matrix material of the microparticles of the present invention must be a biocompatible and biodegradable polymeric material. . . . Suitable examples of polymeric matrix materials include poly (glycolic acid), poly-d,l-lactic acid, copolymers thereof, copolyoxalates, polycaprolactone, poly (lactic acid-caprolactone), and the like."); col. 2:56-3:8 ("The molecular weight of a polymer is also important from the point of view that molecular weight influences the biodegradation rate of the polymer. The drug can also be released from the microparticles as the polymeric excipient bioerodes. By an appropriate selection of polymeric materials a microparticle formulation can be made such that the resulting microparticles exhibit both diffusional release and biodegradation release properties."); col. 10:51-11:5; col. 12:1-4.

Lapka '244: Abstract; col. 2:35-63; col. 4:35-57 ("Among the bioabsorbable polymer materials suitable for use in the invention may be mentioned poly(lactic acid) or polylactic acid polymers, such as dl-poly(lactic acid) (or poly(dl-lactic acid)) polymers, poly-(glycolic acid) polymers, poly(hydroxybutyric acid) polymers and lactide/glycolid copolymers."); col. 4:58-5:5 ("The solid injectable drug material which constitutes the core material of the microcapsules may be any such injectable drug material for which it is desired to establish a long-acting, sustained release delivery system."); col. 32:5-16; col. 32:20-21; col. 32:28-34; col. 32:35-39 ("The process according to claim 8 wherein the core material is selected from the group consisting of cyclazocine, tetracycline, ehtisterone, digitoxin, antimony potassium tartrate, salmon calcitonin, ACTH, lypressin, sommatostatin, and insulin.").

Kent '189: Abstract; col. 1:12-28 ("The invention relates to a microcapsule composition comprising a core containing at least one water-soluble, hormonally active polypeptide and optionally a polymer hydrolysis modifying agent encapsulated in a biodegradable, biocompatible copolymer excipient. These compositions have sustained release characteristics. More specifically it relates to microcapsules wherein the core contains water-soluble polypeptides which are lutenizing hormone-releasing hormones, or mammalian growth hormones or polypeptides having thymosin-like activity and optionally an organic acid or its salts, or an acidic, neutral or basic inorganic salt which is capable of modifying the hydrolysis rate of the polymer excipient, encapsulated by a biocompatible, biodegradable excipient."); col. 1:50-58; col. 2:4-7 ("The encapsulating material may be a synthetic polymer comprising either poly(o-

hydroxycarboxylic acids), poly(lactones), poly(acetals), poly(orthoesters) or poly(orthocarbonates)."); col. 11:5-38; col. 11:39-13:35 ("The number and type of encapsulating excipients which may be effectively used to practice this invention is limited only by the requirements that the material be biocompatible and biodegradable. . . . Various combinations of alpha hydroxycarboxylic acids and certain lactones can be condensed to form such polymers, particularly lactic acid and glycolic acid or combinations thereof. . . . Similar biocompatible polymers based on glycolic acid and glycerol and the like are also known. . . . Several new biocompatible, biodegradable polymers derived from polyorthoesters and polyorthocarbonates also may be effectively used as encapsulating excipients in the practice of this invention. . . . There are also known polyacetals and polyorthoesters useful for this purpose . . ."); col. 17:42-18:67.

Tice '268: Abstract ("A compatible, biodegradable microcapsule delivery system for active ingredients, including hormonally active peptides, proteins, or other bioactive molecules . . ."); col. 1:32-46 ("More recently a polymer of poly(D,L-lactide-coglycolide) (DL-PLG), which is biodegradable and biocompatible with living tissue, has been used in microcapsules for longer acting delivery systems. Systems of microencapsulated active ingredients in polymers and copolymers have been used to achieve controlled release of chemical and biological pharmaceuticals."); col. 1:47-2:14 ("The microcapsule systems described in the above-publications all share a common feature in that the release of the compound is controlled by the porosity and/or erosion of a polymer continuum."); col. 2:45-53; col. 3:40-47 ("It should be noted, however, that other polymers besides poly(D,L-lactide-co-glycolide) may be used. Examples of such polymers include, but are not limited to: polyacetal polymers, polyorthoesters, polyesteramides, polycaprolactone and copolymers thereof, polycarbonates, polyhydroxybuterate and copolymers thereof, polymaleamides, copolyaxalates and polysaccharides."); col. 11:15-41.

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); col. 3:13-18; col. 3:34-38 ("In a preferred technique, one or more finishing coats of a second solution containing the same or another biocompatible polymer without the carrier is applied to provide an impermeable or substantially less permeable outer surface."); col. 4:29-34 ("In this embodiment, active factor 26 is incorporated within the membrane wall 12. The outer membrane surface 28 is nonporous, while porous inner membrane surface 22 allows for the diffusion therethrough of active factor 26."); col. 4:66-5:11 ("The membrane of the channel may be fabricated from any biocompatible polymers, such as, for example, polyethylene vinyl-acetate (EVA). . . . Preferable acrylates include methacrylates or hydroethylmethacrylates. The membrane instead may be composed of a bioresorbable biocompatible polymer, such as a polyanhydride, polyester, or mixtures thereof."); col. 5:18-28 ("In a preferred embodiment of the invention, the outer surface of the membrane is impermeable to solutes of any size, while the inner membrane surface contains pores [that] enable the active factors to diffuse out of the membrane and into the lumen of the channel."); col. 5:44-6:10; col. 6:17-22 ("The layering procedure allows deposition of an impermeable coat on the outer surface of the device, insuring that the active factors incorporated into the membrane walls will be inhibited from diffusing through the external surface, and will diffuse only through the inner membrane surface into the lumen of the channel."); col. 9:18-10:3; col. 10:10-12.

Folkman '560: Col. 1:56-2:23; col. 2:43-68; col. 3:18-23 ("The polymer matrixes, which are suitably used in the present invention, are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:36-51 ("Typical polymeric material suitable for forming the matrix . . . include . . . alkylene-vinyl acetate copolymers . . . crosslinked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:52-4:26 ("In the presently preferred embodiment the polymeric materials useful for forming the matrix are the ethylene vinyl ester copolymers of the general formula . . ."); col. 8:17-18; col. 11:56-12:20; col. 12:28-31; col. 12:36-43; col. 12:52-54 ("The therapeutic system for the administration of insulin according to claim 1, wherein the polymeric matrix is ethylene-vinyl acetate copolymer."); col. 12:59-61.

Cohen '496: Abstract; col. 2:46-66 ("In general, the invention features an improved method of making such a body, in which a biologically active material and the polymer below the glass transition temperature of the polymer and compressing the mixture above the glass transition point of the polymer. In preferred embodiments, the polymer is an ethylene-vinyl ester copolymer of the general formula . . ."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:65-4:39 ("In a presently preferred embodiment, the polymeric materials useful for forming the matrix are the ethylenevinyl ester copolymers of the general formula . . ."); col. 9:40-10:17; col. 10:18-32.

Schiraldi '243: Col. 1:58-60 ("Other polymers that might be added are vinyl copolymers, polysaccharides, gelatin and collagen."); col. 2:30-51; col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 3:14-34; col. 4:67-5:27; col. 10:3-7; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Helwing '868: Abstract ("The compositions may either be in capped form or leashed to a polymeric backbone. . . . The primary uses of the compositions are in controlled release applications such as drugs . . . or in any application where predictable hydrolytic release of the active agent is desirable."); col. 1:6-16 ("The present invention relates generally to compositions of matter and more particularly to covalently bonded compounds composed of active agents containing reactive functional groups The primary uses of the invention are in hydrolysable controlled release utilizations of active agents in such areas as pharmaceuticals,

insecticides, herbicides, and the like."); col. 1:19-37 ("In addition . . . it may be highly desirable to have a system that permits the continuous controlled release of an agent . . ."); col. 1:38-2:11 ("One of the most common methods of achieving predictable controlled release mechanism of an active chemical agent is to encapsulate the agent with another material which gradually degrades in the desired medium. . . . A similar method is to trap molecules of the active agent within a surrounding polymer matrix. The matrix structure is such that exposure to an environmental material, usually water, causes the matrix structure to gradually degrade until the surrounding matrix structure is decomposed to the extent that the active agent molecule is permitted to escape into the environment. . . . The Heller, et al. patent utilizes a polymer structure . . . subject to hydrolysis, that is, it is subject to degradation in a gradual manner upon contact with water."); col. 2:12-24 ("The usefulness of structures such as that taught in Heller, et al. patent is significantly dependent upon the unique bioerodable, or hydrolysable, bonding structure . . ."); col. 2:25-37 ("The bonds so formed between the ketene acetals or vinyl ethers and hydroxyl groups are readily hydrolysable under even mildly acidic conditions. It is postulated that similar results will be obtained between various other functional groups on active agents and ketene acetals or vinyl ethers, and that these linkages will be hydrolysable with degradation of the covalent bond in the presence of water providing an ideal mechanism for controlled release of chemical or biological agents."); col. 38-53 ("In the present invention, as active agents will be bonded directly to the controlled release matrix, specific structural design of the base component system will most directly affect control over the hydrophobicity of the overall matrix."); col. 2:55-3:27; col. 3:37-43 ("It is an object of the present invention to provide an aggregation of useful chemical compounds wherein a chemically active agent via its polar active (PA) functional groups is covalently bonded with a carbonium ion mechanism ("CIM") base group, the bond therebetween being hydrolysable in a predictable manner, resulting in controlled release."); col. 3:47-50; col. 3:62-66; col.3:67-4:17 ("The present invention is an aggregation of compositions consisting of a hydrolysable covalent bond formed between a base structure and an active agent structure. . . . The combinations are particularly adapted for use in controlled release of the active agents by way of hydrolysis. The usefulness of the combinations of the present invention is found in a wide degree of chemical and biological applications including drugs . . ."); col. 4:18-38 ("The inventive compositions of matter have the common property that the covalent bond joining the active agent to the base component is predictably hydrolyzable."); col. 4:39-5:6; col. 5:7-46; col. 5:47-50 ("An advantage of the present invention is that new compositions of matter may be created which are subject to predictable hydrolysis under selected environmental conditions."); col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20 ("Each of the compositions of the present invention has two distinct moieties joined by a hydrolyzable covalent bond. . . . The active component will have this chemical or biological effect when it is in its free molecular form but will not have the same effect when it is restricted in the inventive composition by the covalent bond. The hydrolytic decomposition of the covalent bond will act to release the agent so that it may again act in its original molecular form."); col. 7:21-8:50 ("Polymeric support substrates for the leashed systems would include polyvinyl alcohol, dextran, cellulose and similar polyhydroxy polymers."); col. 8:51-9:29 ("The common thread found in the various active agents is that each include one or more functional PA subgroups which are capable of forming the desired hydrolyzable covalent bond with the CIM subgroups of the base component in a predictable manner."); col. 9:30-52 ("With respect to other active agent functional PA groups and CIM base components, the bond structure will not be a pure orthoester linkage but will be of a similar hydrolyzable nature."); col. 9:64-10:9; col. 10:23-

11:32; col. 11:33-12:48 ("However, in the presence of water, the orthoester-type linkage is subject to hydrolysis as shown in equation EQ-2 and the Z group representing either the ketene acetal or thioacetal."); col. 12:49-13:5 ("The hydrophobicity of the inventive compositions may be altered such that the composition hydrolyzes at different rates."); col. 19:57 ("As is clear from the above, the scope of possible compositions that can be created according to the present invention is extremely broad. . . . All of the inventive compositions are such that they may be created by the process of the present invention and all will be similar in that the CIM and PA groups will form a hydrolyzable covalent bond which will act to keep the inventive composition intact under environmental conditions until hydrolysis occurs."); col. 20:18-37 ("Timed-release drugs for controlled introduction into the blood stream or other body tissues or cavities are well known, including compositions referred to as pro-drugs. The inventive compositions are extremely well adapted for use in this field. . . . Along these lines, the inventive systems could be used to deliver not only general drugs, but cancer drugs, hormones, vitamins, fungicides and even used as a more durable sunscreen."); col. 20:46-54; col. 20:55-68 ("The preferred embodiment of the present invention may also be applied to a surface as a film of uniform consistency for use in several areas of application. . . . The chemically linked nature of the controlled release matrix affords not only the ability to apply such films, but permits the most compact physical structuring possible in a controlled release matrix as well as an assured even distribution of the desired agent."); col. 21:27-41; col. 21:42-46 ("The composition of claim 1 wherein said covalent bond is predictably degradable via hydrolysis such that the active agent component may be released in a controlled release manner under selected environmental conditions."); col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3 ("The composition of claim 1 wherein the covalent bond is destructible via hydrolysis at a predictable reaction rate in a specified environment to yield a hydrolytically degraded base component and the active component as separate molecules."); col. 23:4-col. 24:27.

Valentini '029: Col. 3:15-25 ("The semipermeable nerve guidance channels of the present invention can also be biodegradable.").

Greco '135: Abstract; col. 1:19-26 ("This invention relates to methodology for the surface modification of surgical implants permitting the binding of drugs which, after implantation, are slowly released. More particularly, this invention relates to improved surgical implants having sustained, localized delivery of pharmacological agents such as extended antibiotic activity or reduced thrombogenicity, and methods for producing same."); col. 1:29-2:59 ("The surface modification of surgical implants by the adhesion of pharmacological agents for the purpose of minimizing infection and prosthesis rejection is well-known and has generated broad interest for some time. . . . The present Application is therefore an effort to further disclose and particularize this aspect of the invention, i.e., the development of the antibiotic bonded prosthesis utilizing an anionic surfactant and the oppositely charged drug, antibiotic or other agent or factor."); col. 3:8-19 ("An object of the present invention is to provide improved surfactant-modified implantable devices having a drug, including antibiotics, antithrombogenic agents, thrombolytic agents, disinfectants, etc., bound to the surface thereof. . . . Another object of the present invention is to provide an improved implantable device having a drug bound thereto of improved release times."); col. 3:22-27; col. 3:30-43; col. 4:2-39; col. 5:30-6:58 (disclosing process by which antibodies can be bound to thermoplastic substrates); col. 7:46-9:3; col. 9:10-12.

Bawa '279: Abstract; col. 1:16-36; col. 2:27-35 ("With the foregoing and other objects in view, the invention herein provides a sustained-release polymeric hydrogel dosage form useful for topical, systemic or transdermal administration of a medicinal agent comprising one or more polymerizable hydrophilic polymers, an ion-exchange resin, a cross-linking agent and optionally one or more hydrophobic polymers."); col. 2:39-46; col. 2:47-68 ("The preferred hydrophilic monomers are the hydroxyalkyl esters, specifically hydroxyethyl methacrylate (HEMA)."); col. 4:14-25; col. 6:40-44 ("The invention contemplates a variety of processes for preparing the sustained-release polymeric hydrogel dosage form whereby the medicinal agent is retained by the polymeric matrix and, upon tissue contact, is gradually released into the tissue."); col. 7:15-21; col. 8:1-6; col. 8:29-49; col. 8:54-55; col. 8:66-68; col. 11:42-54; col. 13:10-17; col. 13:26-14:14.

Aebischer '627: Col. 3:23-49 ("In addition, these polymeric materials have the capacity for sustained release of the embedded substance at a controlled rate."); col. 3:57-4:3 ("The polymeric insert includes pores having a molecular weight exclusion of from about 1 kD to about 1,000 kD, but preferably from about 25kD to about 100 kD. In one preferred embodiment, the polymeric insert includes a hydrophobic matrix such as ethylene-vinyl acetate copolymer."); col. 6:52-59 ("the insert may be composed of any biocompatible material having the desired pore size and being composed of materials which do not limit the activity of the substance embedded therein. . . . [H]ydrophobic matrices such as ethylene vinyl acetate are particularly useful."); col. 7:3-12 ("One way of providing the source of neurotransmitter include incorporating it into the polymeric insert. The encapsulating material provides a protective environment for substances such as neurotransmitters or cell growth factors embedded therein, while affording sustained release of the substance at a controlled rate therefrom."); col. 7:13-28; col. 7:29-56 ("The release rate may also be controlled by the amount of pure, impermeably polymeric material coating the effector substance-embedded insert; the more (or thicker the) coatings, the slower the release rate. Materials such as polyurethane or pure ethylene-vinyl acetate are particularly useful for this purpose."); col. 10:31-34 ("To retard dopamine release, three coats of 10% EVAc were applied to each rod by repeated immersion . . ."); col. 14:29-32; col. 14:45-49; col. 14:57-58.

Wood '066: Abstract ("A controlled-release bandage containing therapeutic agents in a poly(vinyl alcohol) cryogel is disclosed. The bandage may include . . . hydrophobic particles to further insure controlled and constant release of therapeutic agents."); col. 2:56-66 ("Bandages comprising cryogel and therapeutic agents are used to provide a protective covering and to provide a controlled and uniform administration of therapeutic agents to sites of trauma such as wound, thermal or chemical burns, ulcers, lesions or surgical sites. Cryogel bandages may include . . . particles having hydrophobic properties, which absorb the therapeutic agent and release it in an uniform and controlled manner."); col. 3:47-4:36; col. 7:6-32 ("The release of therapeutic agents from the bandage has been found to be further controllable by including insoluble particles capable of adsorbing or forming salts with the therapeutic agent in the bandage. . . . Other examples of suitable insoluble particles include hydrophobic resins, silica, hydroxyl apatite and aluminum oxide."); col. 7:43-50; col. 8:55-56; col. 26:8-18 ("The bandage of claim 1 wherein the insoluble particles capable of adsorbing or forming salts with the therapeutic agent are a hydrophobic resin particles.").

Strecker '746: Abstract; col. 1:63-2:2; col. 2:21-32; col. 3:5-17 ("Another sensible advanced version is characterized in that medications in the lining are dissolved in the wrapping material or included in the form of beads."), ("It can be practical for there to be more or less openings in the wall of the lining next to the lumen than there are in the wall next to the inner surface of the vessel. The ratio can be exploited to prescribe the dosage of medication to the lumen or wall of the blood vessel."); col. 3:17-26 ("The wrapping material can also to advantage be biodegradable When the material is biodegradable, the medication will be released not by diffusing out of the vehicle but by escaping as the vehicle that the medication is dissolved in or that accommodates the beads that encapsulate the medication at its surface decomposes and by accordingly coming into contact with body fluids."); col. 3:27-33; col. 5:10-12; col. 5:38-41; col. 6:1-17; col. 6:35-38; col. 7:16-37 ("a lining impregnated with medication for delivery to a wall of said body lumen"); col. 7:48-65; col. 8:19-10:19; Figs. 7 & 8.

Lambert '246: Abstract ("The biologically active compound is, therefore, released only at the site where it is desired, i.e., where the prosthetic article is positioned."); col. 1:46-55 ("Release of heparin from intravascular catheters in quantities sufficient to decrease thrombosis on the catheter has been achieved by either covalently bonding a charged molecule to a polymer or incorporating a large nonmobile charged molecule on the surface of the polymer . . ."); col. 1:57-61; col. 2:15-34 ("Increasing the lipid solubility of the compound slows release from the polyurethane, and increases the tissue retention. More lipid soluble compounds are, therefore, preferred agents for use in the practice of the present invention."); col. 2:38-40 ("In accordance with the present invention, there is provided a method for preparing a system suitable for localized delivery of biologically active compounds to a subject."); col. 2:40-49; col. 2:53-65; col. 7:31-33 ("The results of this example demonstrate that polyurethane stent coatings can concentrate and release lipophilic drugs in vitro."); col. 8:58-9:4 ("Adventitia overlying the stent contained 360 times the concentration of forskolin in the blood and 305 times the concentration of forskolin in the contralateral artery. . . . In a similar model, etretinate, a retinoic acid analog, develops concentrations in the media of 250 ng/mg tissue at 24 hours. At 24 hours, this concentration was over 2000 times the concentration in the blood."); col. 9:31-37 ("These data demonstrate that a polyurethane coated nitinol stent is capable of delivering a lipophilic drug in high local concentration in the vessel wall. The large 450 fold differential of local tissue levels of forskolin over blood levels reflects the capability of this delivery system to provide high local concentration and potentially higher efficacy, with lower risk of systemic side effects."); col. 10:47-50; col. 10:62-64 ("The drug delivery system of claim 1 wherein the biological agent is absorbed substantially throughout the entire thickness of the polyurethane elastomer coating."); col. 11:16-17 ("The drug delivery system of claim 8, wherein said biologically active compound is a lipophilic compound."); col. 11:30-31; col. 11:36-40; col. 12:12-13; col. 12:17-21; col. 12:53-54.

Bellamkonda '029: Col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 5:32-48 ("The agarose hydrogels of this invention may be used as a carrier to present various ECM proteins or peptides We prefer covalent

immobilization of ECM proteins to the hydrogel backbone."); col. 7:26-32 ("In a preferred embodiment, laminin-derived oligopeptidic fragments . . . are coupled to the hydroxyl backbone of agarose, using any suitable method."); col. 9:36-48 ("These growth factors may be incorporated into the channel membrane . . ."); col. 11:7-8 ("Additionally, the membrane may be composed of a biodegradable material."); col. 11:41-50; col. 12:13-16 ("Preferably the permselective membrane is fabricated to be impermeable to some of these substances so that they are retained in the proximity of the regenerating nerve ends."); col. 12:42-49; col. 12:50-56; col. 15:67-16:17; col. 23:54-24:55.

Dayton '382: Abstract ("The stent is then coated with a polymer . . . which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids, with the equilibrium being controlled by charge distribution, concentration and molecular weight of the bioactive substance in relation to the pore size of the polymeric carrier for controlled prolonged release of said bioactive substance."); col. 1:9-17 ("The present invention relates to an improved percutaneously inserted endoprosthesis device which is permanently or temporarily implanted within a body vessel, typically a blood vessel. More particularly, the present invention relates to a new procedure for administering localized bioactive substances via prosthesis designs . . ."); col. 3:36-39; col. 3:62-4:17 ("Among these polymers are polymers having a microporous structure, such as . . . biodegradable polylactic acid polymers, polyglycolic acid polymers . . ."); col. 4:24-33 ("A bioactive substance is preferably admixed in the polymer for elution from the microporous structure of the stent or coating on the stent after implantation. The rate of elution of the bioactive substance is controlled by selecting a pore size for microporous structure . . ."); col. 6:64-7:7 ("Also included in the polymer is a bioactive substance having a charge distribution, concentration and molecular weight selected which achieves an equilibrium in relation to the pore size of the polymeric carrier with said surrounding body tissues or fluids."); col. 7:8-14; col. 7:20-23.

Burt '036: p.4:19-33 ("Within one aspect of the present invention, compositions are provided . . . comprising (a) an anti-angiogenic factor and (b) a polymeric carrier. A wide variety of molecules may be utilized within the scope of the present invention as anti-angiogenic factors Similarly a wide variety of polymeric carriers may be utilized, representative examples of which include poly(ethylene-vinyl acetate) . . . and copolymers of polylactic acid and polycaprolactone."); p.10:17-25; p.14:9-27; p.21:2-4; p.51:1-52:35.

Goldin '568: Abstract; col. 1:21-34 ("In certain circumstances, another desirable use of controlled release methods is to target the delivery of a therapeutic agent specifically to the tissue or site that can benefit from the presence of such an agent."); col. 1:35-41 ("Several classes of controlled release strategies have been developed, principally involving: (a) release by controlled diffusion; . . . and (c) release limited by chemical control of the interaction of the agent with a substrate to which it is adsorbed or bound."); col. 1:43-62 ("Release by controlled diffusion may be accomplished by means of containment of the therapeutic agent within a substrate whose small pore size and/or tortuosity of diffusion path thereof limits the diffusion of said agent through the substrate. . . . The therapeutic agent can be incorporated within the diffusion-limiting substrate Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:8-16 ("Towards that end, diffusion-controlled slow release devices have

been fabricated from biodegradable polymers . . ."); col. 2:24-28; col. 3:42-53 ("Release by chemical control most commonly involves chemical cleavage from a substrate to which a therapeutic agent is immobilized, and/or by biodegradation of the polymer to which the agent is immobilized."); col. 3:54-65 ("Another variant of release by chemical control termed herein "controlled noncovalent dissociation or 'CND'", relates to release resulting from dissociation of an agent that is bound temporarily by non-covalent binding of the agent to a substrate."); col. 4:25-45 ("The microskin is specifically tailored to bind macromolecules . . . noncovalently by cooperative secondary bonds, and slowly release the macromolecules by controlled non-covalent dissociation (CND)"); col. 4:63-66; col. 6:1-19 ("Because preferred embodiments of the CND controlled Release Device and methods of use thereof employ membranes whose pore size is normally much greater than molecular dimensions, the kinetics of release are governed primarily by the strength and number of the reversible cooperative secondary bonds which immobilize said protein for CND."); col. 6:20-29 ("Limitation of the toxicity associated with the macromolecules to be released results from selective delivery to the site of action in the amounts and at the time needed. While in practice, the temporal and spatial selectivity of the current invention may not be absolute, it is clearly an improvement over more conventional modes of delivery . . ."); Fig. 1A; Fig. 1B; col. 8:65-9:6; col. 9:18-22; col. 9:23-30; col. 9:43-50 (" . . . delivery from controlled release devices can be controlled by diffusion out of said device, dissociation of chemical bonds, and the like."); col. 9:51-55; col. 10:45-54; col. 17:40-54 ("[S]ynthetic polymers . . . may be derivatized to attach functional groups which may react under appropriate circumstances to form covalent bonds with the macromolecules one wishes to bind and release in a controlled manner."); col. 20:9-12 ("By appropriate use of said Device, one can selectively target a therapeutic site . . ."); col. 20:46-21:19 ("[W]hen the pore size of the underlayment and/or the microskin approaches submicron dimensions and/or the thickness of said Devices approaches millimeter dimensions or greater, diffusion of the agent to be delivered out of said device may contribute to or even be the predominant process governing controlled release from said Device."); col. 21:47-49 ("A coating of a permeable guide tube, with a secondary membrane designed to exclude macromolecules from without."); col. 27:10-18; col. 32:26-31.

Palmaz '762: Col. 10: 28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '337: Col. 9: 24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Zaffaroni '254: col. 2:6-9 ("Still another approach has been to enclose the drug within a single capsule having a polymeric wall or walls through which the drug can pass, for example, by diffusion."); col. 2:16-26 ("Additionally, these prior art devices have generally been based on the use of a single material, such as silicone rubber polymers, especially polydimethylsiloxane, as the diffusion control membrane. In large part, these polymers were selected because of their permeability to some important drug molecules. But, it has been found that mere high permeability without consideration of release rate controlling properties can be a significant

disadvantage which defeats the primary object of an acceptable drug delivery device."); col. 4:54-58 ("In operation, solid drug carrier 13 serves as a reservoir 12 by supplying dissolved drug 14 to the micropores 15 of wall 11 as drug molecules move through the carrier to bathe the inner surface of wall 11."); col. 7:18-25.

Langer I: p.29 ("In the bioerodible system, the drug is distributed relatively uniformly throughout the plastic as in matrix systems, but it differs from the matrix in that its plastic portion decreases with time. As the plastic surrounding the drug is eroded, the drug escapes. . . . The most popular bioerodible polymers have been absorbable suture materials such as polylactic acid."); p.29-30 ("The second type of chemically controlled system is known as a pendant chain system. In simplest form, the drug is attached via chemical bonds to a polymer backbone. It could also be attached via a spacer group Release occurs when water reacts to break those bonds, thereby freeing the drug. Release rates are adjusted by varying the hydrophilicity of the polymer backbone. Systems could also be designed so that an enzymatic reaction could break the drug-polymer bonds."); p.29 Figure legend ("Chemically controlled pendant chain drug-delivery system. Here, the drug is bound to a polymer backbone and released by hydrolytic or enzymatic cleavage, the key to controlling the medication's delivery.").

Langer II: p.217-18 ("In chemically controlled systems, release is accomplished either by biodegradation of the polymer . . . or by chemical cleavage of the drug from a polymer backbone to which the drug had been bound as a pendant group."); p.218 Fig. 3; p.219 Fig. 4 ("Chemically controlled pendant-chain drug-delivery system. Here, the drug is bound to a polymer backbone and released by hydrolytic or enzymatic cleavage."); p.221-225 ("Contraception" "Immunization" "Anticoagulation" "Cancer" "Insulin Delivery" "Controlled-release formulations may be applied to other clinical areas, including the release of narcotic antagonists, antibiotics, interferons, anesthetics, anti-arrhythmics, and antimalarial drugs.").

Langer III: p.25 ("Matrix Systems"); p.26-27 ("From a chemical standpoint, Heller has considered bioerodible systems in terms of three dissolution mechanisms: [1] water-soluble polymers insolubilized by degradable cross-links; [2] water-insoluble polymers solubilized by hydrolysis, ionization, or protonation of pendant side-groups; and [3] water-soluble molecules. These mechanisms represent extreme cases, and erosion by a combination of mechanisms is possible."); Fig. 3-3; Fig. 3-4; p.27-28 ("In pendant chain systems, a drug is chemically bound to a polymer backbone-chain and is released by hydrolytic or enzymatic cleavage. . . . The polymer system can be either soluble or insoluble . . . insoluble forms are more desirable for long-term controlled-release implants. The backbone may also be biodegradable or nonbiodegradable. . . . The drug itself can be attached directly to the polymer or attached via a spacer group. The spacer group may be used to affect the rate of release and hydrophilicity of the system.").

Langer & Peppas: Fig. 5; p.80-83 ("Matrix Systems"); p.83 ("Polymers for Diffusion-Controlled Systems"); p.84; p.85 ("Ethylene-vinyl acetate (EVA) copolymers have found major applications in controlled release of bioactive agents because of their relatively good chemical stability, biocompatibility, and inertness."); Fig. 7; p.86-87 ("Chemically controlled drug release generally involves one of two types of systems: 1) Erodible systems in which the drug is dispersed in a biodegradable polymer and drug release is influenced by the rate of degradation of the polymeric material, and 2) pendant chain systems in which the drug is attached to a polymer

through a hydrolytically or enzymatically labile linkage. Drug release is influenced by the rate of degradation of this linkage."); Fig. 8; p.87-100 (describing and identifying polymers for biodegradable drug release systems); p.100-101 ("In [pendant chain systems] a drug is chemically bound to a polymer backbone and is released by hydrolytic or enzymatic cleavage. . . . [I]nsoluble [backbones] are more desirable for long-term controlled-release implants. . . . The drug itself can be attached directly to the polymer or it can be attached via a spacer group. The spacer group may be used to affect the rate of release and hydrophilicity of the system. To achieve near constant release, the cleavage of the drug from the polymer must be the rate-limiting step. . . . There has recently been interest in developing controlled-release systems using pendant chain polymers for clinical applications."); p.114-16 ("Medical applications of controlled-release systems can be divided into four general areas: oral systems, transdermal systems, external implants, and subcutaneous implants.").

Langer IV: p.36 ("In matrix systems, the drug is uniformly distributed through a polymer."); Fig. 2; p.37 ("Two systems of chemical control exist. The first mechanism is bioerosion or biodegradation of the polymer. As the polymer surrounding the drug is eroded, the drug escapes. . . . The second type of chemically controlled system is known as a pendant chain system. In simplest form, the drug is attached via chemical bonds to a polymer backbone. It could also be attached via a spacer group. Release rates are adjusted by varying the hydrophilicity of the polymer backbone. Systems could also be designed so that an enzymatic reaction could break the drug-polymer bonds."); p.37 Fig. 3 ("Idealized diagram of the cross-section of a cylindrical or spherical bioerodible matrix."); p.37 Fig. 4 ("Idealized diagram of a chemically controlled pendant chain drug delivery system. The drug could be connected to the polymer backbone as shown or could be coupled to a spacer group attached to the polymer backbone."); p.41-42 ("The second type of [contraceptive] system is a subdermal implant composed of a biodegradable polymer."); p.44 ("Small (0.3 mm³) injectable pellets of ethylene-vinyl acetate copolymer containing 100 ug of a test antigen, bovine serum albumin, were positioned subcutaneously in mice.").

Langer V: p.24 (" Examples of polymers with these properties include nondegradable polymers such as ethylene-vinyl acetate copolymers (EVAc), and biodegradable polymers such as polylactic or polyglycolic acid.") ("Theoretically, the [biodegradable] polymers should have a hydrophobic backbone, but with water-labile linkage.").

Langer VI: p.115 (One approach that has received increasing attention as a means of prolonging drug release has been the incorporation of drugs in solid polymers (e.g., silicone rubber, ethylene-vinylacetate copolymer). This method permits drugs to be released for long time periods in a controlled fashion."); p.120-124 ("The ideal [biodegradable] polymer would have a hydrophobic backbone, but with water labile linkage.").

Laurencin & Langer: Fig. 2; p.304-306 ("Matrix Systems"); p.306-307 ("Three dissolution mechanisms for bioerodible polymeric devices are found in general: Type 1: water soluble polymers that are made insoluble through crosslinks that are degradable. On exposure to an aqueous environment, crosslinks are broken, polymer dissolves, and release occurs. Type 2: water insoluble polymers that on exposure to an aqueous environment are solubilized by hydrolysis, ionization, or protonation of pendant side groups. Type 3: water insoluble polymers

containing hydrolytically unstable backbone linkages. On exposure to an aqueous environment, polymer chains are cleaved to small water soluble monomers."); p.307 Fig. 4; p.308-309 ("In [pendant chain systems], drug is chemically bound to the backbone of a polymer. Release takes place by hydrolytic or enzymatic cleavage. . . . Polymer systems can be soluble or insoluble, and the backbone itself may be bioerodible or nonbioerodible. Soluble backbone chains are generally used for transport functions such as cell targeting; insoluble forms are more desirable for long-term controlled release implants. Drug can be chemically attached to the polymer directly or through a spacer group. The spacer group may be used to affect the rate of release or hydrophilicity of the system."); p.308 Fig. 5 ("Chemically controlled pendant chain drug delivery device. Drug bound to polymer backbone is released by hydrolytic or enzymatic cleavage."); p.313-316 (clinical applications of EVAc and biodegradable polymers).

Langer VII: p.1529 ("Chemical control is accomplished either by polymer degradation or chemical cleavage of the drug from a polymer."); p.1529 Fig.1(B), (C) and (D); p.1530 ("Examples of polymers that perform in this way are non-degradable ethylene-vinyl acetate copolymer and degradable lactic acid-glycolic acid copolymers."); p.1531-32 ("Theoretically, the [ideal surface-eroding] polymer should be hydrophobic but should have water-labile linkages.").

Langer & Moses: p.341-42 ("[W]e proposed that an ideal polymer would have a hydrophobic backbone, but with a water labile linkage."); p.342-44 ("One such report . . . employed the porous ethylene-vinyl acetate copolymer (EVAc) system to provide sustained release of fibroblast growth factor (FGF) or epidermal growth factor (EGF).").

Chien: p.32-33 ("[The hydrolysis-activated] controlled drug delivery system depends on the hydrolysis process to activate the release of drug molecules. . . . The release of a drug from the polymer matrix is activated by the hydrolysis-induced degradation of polymer chains and controlled by the rate of polymer degradation.") ("[The enzyme-activated] controlled drug delivery system depends on the enzymatic process to activate the release of drug. . . . The release of drugs is activated by the enzymatic hydrolysis of the biopolymers by a specific enzyme in the target tissue."); p.37 ("An ideal site-targeting drug delivery system has been proposed . . . constructed from a nonimmunogenic and biodegradable polymer backbone having . . . a drug moiety that is covalently [sic] bonded to the polymer backbone through a spacer and contains a cleavable [sic] group that can be cleaved only by a specific enzyme(s) at the target tissue.").

Thomson: p.34-36 ("The degradation of synthetic polymers is, in general, brought about by simple hydrolysis, although in some cases enzymatic processes assist in the degradation mechanism.").

Hanes & Langer: p. 647 ("Polymers can also be used to deliver vaccines in a controlled manner."); p.648 ("Biodegradable polymeric devices or pendant chain systems are examples of chemically controlled devices. In the former, molecules are typically dissolved or entrapped in a biodegradable, bioresorbable polymer matrix As the polymer degrades and erodes, molecules are released to the surroundings. In pendant chain systems, molecules are chemically attached to the backbone of a polymeric carrier using hydrolytically or enzymatically degradable bonds. In this case, the molecules are liberated as the bonds holding them to the polymer are

cleaved."); p.649 Fig. 29.2; p. 652 ("For the present development of vaccine delivery systems, the use of biodegradable polymers presents significant advantages over the use of nondegradable systems."); p.654-55 ("There are many such polymers that may prove useful for controlled delivery of vaccines; however, no degradable polymer systems has been more widely studied with respect to release kinetics than the lactide/glycolide polyesters."); p.655-56; p.656-58 ("Advantages of Controlled Release for Immunization").

Batz: p.26-27 ("Based on their chemical structure polymeric drugs are divided into the following three groups . . . b) Drugs in which the active substance of known biological activity is bound to a polymeric carrier molecule via a functional group."); p.36-43 ("Polymeric drugs formed by covalent bond of known active components to soluble macromolecular carriers"); p.48 ("Polymeric Forms of Deposit Without Covalent Bond Between Drugs and Polymeric Materials.").

Donaruma: p.10 ("Allan, Chopra, Neogi, and Wilkins, in studies concerned with the design and synthesis of controlled release pesticide polymer combinations, investigated the duration of effectiveness of various herbicidal phenoxyacetic acids chemically bound as pendant substitutes to natural or synthetic water-soluble and water-insoluble polymers."); p.17, 19-20 ("[I]t can be seen that in some cases portions of the polymer repeat unit are structurally constituted so that by hydrolysis the polymer chain or a pendant group may be sundered by hydrolysis. . . . Chemically combining a drug in a polymer may offer a means of sustained release and/or prolonged activity of drugs and/or drug latention. These are not new concepts, and examples are reported in the literature.").

Harris I: p.334 ("As reported in this review, our work has involved the syntheses and evaluation of polymers containing pendant aquatic herbicides."); p.344 ("The herbicide release rates of polymers containing herbicides as pendant substituents are extremely slow in water with pH=C at 30°C. The herbicide release rates, however, can be increased by incorporating hydrophilic groups along the polymers' backbones").

Feld: p.113-15 ("One approach to obtaining these formulations has been the synthesis of polymers that contain pesticides as pendent side chains. . . . Pesticide release occurs by the slow, sequential hydrolysis of the pesticide-polymer chemical bonds. This provides a sustained release of the pesticide over an extended period of time. The actual release depends on the nature of the pesticide polymer bond and the dimensions and structure of the resultant macromolecular combination."); p.116-17 ("It was postulated that increasing the length of the pendent side chain would enhance the hydrolysis of the herbicide-polymer bond."); 117-19 ("Herbicide reactivation was produced enzymatically using lipase, acetylcholinesterase and trypsin.").

Harris & Post I: p.622 ("One approach to obtaining controlled-release pesticide formulations that contain a high percentage of pesticide has been the synthesis of polymers that contain pesticides as pendent side chains. The pesticide is presumably released by the slow sequential hydrolysis of the pesticide-polymer chemical bonds. . . . It was postulated that increasing the length of the pendent side chain would enhance the hydrolysis of the herbicide-polymer bond.").

Harris & Post II: p.225 ("One approach to obtaining controlled-release pesticide formulations that contain a high percentage of pesticide has been the synthesis of polymers that contain pesticides as pendent side chains. The pesticide is presumably released by the slow sequential hydrolysis of the pesticide-polymer chemical bonds. . . . It was postulated that increasing the length of the pendent side chain would enhance the hydrolysis of the herbicide-polymer bond.").

Drobnik: p.2833 ("Water-soluble copolymers based on poly[*N*-(2-hydroxypropyl)methacrylamide] and bearing in their side chains a chromogenic substrate for chymotrypsin were prepared by direct copolymerization or polymeranalogous reaction."); p.2834 ("The bonding of drugs onto macromolecules is an old idea, because it offers a potential optimization of the pharmacokinetics of drugs. The majority of pharmaceuticals are inactive in the macromolecular form and must, therefore, be released in their original active low-molecular weight form, i.e. their attachment to the polymer must be reversible, or degradable."); p.2844-47 ("The results also indicate the general influence of the spacer: the longer the spacer, the easier the cleavage of the enzyme susceptibility bound For practical purposes, that is, enzyme-specific binding of drugs to polymers, the following conclusions can be drawn from the above results . . .").

Allan I: p.17 ("These materials are chemical or physical combinations of known and established pesticides with macromolecules. . . . As the pesticide-polymer combination lies in the soil, a gradual decomposition occurs, and the pesticide is slowly released over the desired and predictable period of time."); p.18-19 ("This situation is avoided by the use of a chemical combination of the butyric acid [herbicide] with the polymeric components of bark. The ester linkage joining the herbicide to the bark will not be easily attacked by any β -oxidase and the butyric acid herbicide is thereby stabilized. Essentially, the only butyric acid herbicide available for β -oxidation is that continuously being released from the bark. This release will occur whether the combination lies in or on the surface of the soil since attack by moisture, micro-organisms and the weather can occur in either of these zones.").

Allan II: p.349 ("We have therefore investigated the potential of pesticide-polymer combinations as a means of securing controlled release of a biodegradable pesticide in approximately the correct amount needed over an appropriate period of time. . . . Two distinct approaches are not reported. (a) Pesticide release by diffusion through polymers, and (b) pesticide release by degradation of a polymer containing the pesticide as a pendent side chain. . . . For case (b) the pesticides . . . are chemically attached as a pendent substituent to a natural or synthetic water-soluble or insoluble polymer . . ."); p.350 ("In the biological environment, side chain degradation occurs so that the chemical bonds holding the pesticide within its polymeric prison are sequentially broken to provide a sustained release of the pesticide over an extended period of time. The rate of release will clearly be determined by the nature of the pesticide-polymer bonds, the chemical characteristics of the pesticide and polymer and the dimensions and structure of the resultant macromolecular combination.") ("Although developed for developed for forest pest control the systems described should be broadly applicable to the controlled release of other biologically active substances.").

Allan III: p.173: ("Controlled release from polymeric matrix"); p.173-74 ("Representative of the other end of the thermodynamic spectrum is the situation where the pesticide is firmly attached to the substrate by a high energy covalent bond. Release of the pesticide then involves the cleavage of a definite identifiable chemical bond such as an ester or amide. . . . The simplest [arrangement] has the pesticide attached as a pendent substituent to a natural or synthetic water-soluble or insoluble polymer having a replaceable hydrogen The chemical bonds holding the pesticide within its polymeric prison are sequentially broken to provide a sustained liberation of the pesticide over an extended period of time."); p. 176 ("Moreover, the [controlled release] concept is broadly applicable to the release of other biologically active substances.").

Jakubke: p. 281 ("Observations in our laboratory indicated that an enzymatic cleavage of carrier-bound biologically active substance of low molecular weight is fundamentally possible. As part of a general model study of enzymatic reactions with insoluble substrates we investigated the α -chymotrypsin-catalyzed hydrolysis of Sepharose-bound L-phenylalanine 4-nitroanilide. As a spacer, 1 or 2 mol of 6-amino-hexanoic acid, respectively, were inserted between the gel matrix and the low-molecular weight substrate."); p. 282 ("The course of hydrolysis was proportional to time during the first 15 min. About 70% of total bound (ϵ Ahx)₂-Phe-NA was hydrolyzed after 4 hr."); Fig. 2 ("Dependence of hydrolysis on the enzyme concentration at 25°C."); p. 283 ("In agreement with this the substrate dependence of the hydrolysis rate shows the same course as observed with Glt-Phe-NA.").

Engelberg & Kohn: p. 292 ("For example, degradable polymers are now being investigated as intra-luminal grafts, stent-like devices that are implanted into coronary arteries in an attempt to prevent the collapse and the reblocking (restenosis) of blood vessels after successful balloon angioplasty."); p.293 ("Since surface-eroding, slab-like devices tend to release drugs embedded within the polymer at a constant rate, poly(ortho esters) appear to be particularly useful for controlled release drug delivery. It is not surprising that there are a significant number of publications describing the use of poly(ortho esters) for drug delivery applications."); p. 293-94 ("PLA, PGA and their copolymers are also being intensively investigated for a large number of drug-delivery applications. . . . PLA, PGA and their copolymers are currently the most widely used synthetic degradable polymers in human medicine."); p.294, Table 1; 294-95 (The potential applications of these [PHB polymers] include biomedical applications such as controlled drug release . . ."); p.295 ("Later, it was discovered that PCL can also be degraded by a hydrolytic mechanism under physiological conditions. Under certain circumstances, cross-linked PCL can be degraded enzymatically, leading to enzymatic surface erosion."); p.296 ("It is interesting to note that despite its versatility, PCL has so far been predominantly considered for controlled-release drug-delivery applications.") ("The low hydrolytic stability] was later recognized as a potential advantage by Langer et al. who suggested the use of polyanhydrides as degradable biomaterials."); p. 297; p. 298 ("Poly(ortho esters)"); p. 298-99 ("PGA"); p. 299 ("PLA"); p. 300 ("PBH and copolymers with HV"); p. 301 ("PCL") ("Because of their low mechanical strength and high hydrolytic reactivity, the two polyanhydrides tested appear to be limited to drug-delivery applications."); p. 302.

Roseman & Mansdorf: p. 91-105 ("The objective of this chapter is to describe the development of a bioerodible polymer implant that would release an incorporated drug by zero-

order kinetics for at least 6 months. A further objective is the development of a system where drug release and polymer erosion take place concomitantly so that no polymer remains when the drug is depleted."); p. 107 ("There have been, however, studies where polymer-drug complexes have been synthesized, the major objective of which was to provide a controlled or prolonged action of the drug by the natural hydrolysis or biological scission of the covalent polymer-drug bond. In this way, mescaline, insulin, salicylic acid, D-isoproterenol, naloxone, plant cytokinins, 2,4-dichlorophenoxyacetic acid, norethindrone, and cortisol-21-acetate have been attached to and released from various synthetic and natural polymers through covalent bonds such as amide, ester, aso, carbamate, carbonate, oxime ester, and hydrazone."); p. 108 ("GAGs are biodegradable by enzymatic means normal to the host."); 108-109 ("We have taken advantage of various types of functional groups available on the GAG backbone (carboxyl, primary and secondary hydroxyl, and sulfate) in preparing and testing a series of complexes in which the drug was bound directly to the polymer or via an intermediate linking group such as an amino acid or other such bioacceptable entity. . . . Current work with other drugs bound to the GAG backbone by the same and different bond types (i.e., carbamate, ionic) will be reported in the near future."); p.110; p. 111 ("Amide and ester bond types were chosen because both are susceptible to chemical hydrolysis and both are prevalent naturally and thus are potentially dependable by enzymes."); p. 112 Fig. 2 & 3; p. 112-113 ("The release was pseudo-first order with a release rate constant of 0.10 day^{-1} and a half-life of 3.8 days. This is what one would expect if the rate-determining stem for release is the chemical hydrolysis of the ester bond in the prodrug."); p. 113 ("Reactions on polymers, such as the hydrolytic cleavage of GAG-drug bonds, has been shown to be affected by polymer chain length and conformation, steric isolation, and neighboring group effects."); p. 114; p. 115 ("Even though the amid bond between the drug and the polymer may hydrolyze slowly over this period and release cysteine, the rate-determining step for release was probably enzymatic breakdown of the complex. . . . A large advantage of using glycosaminoglycans as drug carriers is that they are biocompatible and biodegradable."); p.116 ("Chloramphenicol-GAG ester complexes released Cpl quickly by scission of the ester bond. Cysteine-GAG amide complexes degraded much more slowly and probably through enzymatic hydrolysis of the polymer or polymer-drug bond."); p. 117 ("Nevertheless, this concept provides an interesting base from which to design a drug release system; the rate of release may in principle be engineered by the judicious choice of drug-GAG bond based on the hydrolytic stability of the bond.").

Lee & Good: p. 2; p. 2-3 ("As a result of research on improved absorbable sutures, poly (lactic acid), poly (glycolic acid), and lactic/glycolic acid copolymers, which hydrolyze to natural metabolites, have been developed for drug delivery purposes."); p. 3 ("[P]olymer erosion can be controlled by the following three types of mechanisms: (1) water-soluble polymers insolubilized by hydrolytically unstable cross-links; (2) water-insoluble polymers solubilized by hydrolysis, ionization, or protonation of pendant groups; (2) hydrophobic polymers solubilized by backbone cleavage to small water soluble molecules. . . . [O]ther commonly used bioerodible/biodegradable polymers include polyorthoesters, polycaprolactone, polyaminoacids, polyanhydrides, and half esters of methyl vinyl ether-maleic anhydride copolymers.") ("Drug-Polymer conjugates. This system involve drug molecules chemically bounded to a polymer backbone. The drug will be released through hydrolytic or enzymatic cleavage. . . . The attachment of drugs to macromolecular carriers alters their rate of excretion from the body and provides the possibility for controlled release over a prolonged period. . . . Both natural

polymers such as polysaccharides and synthetic polymers such as polylysine, polyglutamic acid, polyphosphazenes, copolymers of vinylpyrrolidone, copolymers of 2-hydroxypropylmethacrylamide, and etc. have been used as drug carriers."); p. 4 ("The drug-polymer linkage may be covalent, ionic, or through some weaker secondary molecular forces. The drug may be part of the polymeric backbone or attached to the side-chain either directly or through a spacer group. The spacer groups is generally selected in such a way that it may be hydrolyzed or degraded enzymatically under specific environmental conditions. Examples of such drug-polymer conjugates include the attachment of ampicillin, 6-amino-methacrylamide copolymers, methotrexate to poly (L-lysine), and norethindrone to poly(hydroxyalkyl)-L-glutamine. In addition to diffusion rate limitations as described in the next section, the drug release rate is primarily governed by the rate of cleavage of the drug from the polymer."); p.5- 7 ("Matrix Diffusion"); p. 7 ("Polymer Erosion. The release of a dissolved or dispersed drug from an erodible polymer matrix can be controlled by a variety of mechanisms ranging from hydrolysis/enzymatic cleavage as discussed in the previous section to swelling and dissolution."); p. 17 ("An important example of these processes is the controlled release of bioactive molecules from polymeric membranes. Many pharmaceutically active agents have been released at controlled rates from hydrophobic polymer carriers. . . . In 1976 it was demonstrated that hydrophobic polymers, in particular ethylene-vinyl acetate copolymer (EVAc), could be used to release molecules with molecular weights greater than 1000."); p. 182 ("Enzyme-Degradable Hydrogel"); p.188-200; p. 214-230.

Langer & Folkman I: p. 179 ("Therefore, we turned to other polymers such as ethylene-vinyl acetate copolymer . . ."); p. 180-83; p. 183-84 ("Poly(vinylalcohol), Hydron, and ethylene-vinyl acetate copolymer were examined for their ability to release soybean trypsin inhibitor . . ."); p. 185-88; col. 188-191 ("The following three studies demonstrate that the pellets are releasing macromolecules in biologically active form."); p. 191-92 ("The present experiments show that macromolecules with a wide range of molecular weights can be delivered in significant quantities from polymeric vehicles that are not inflammatory when implanted in animals. These polymers can release macromolecules in biochemically and biologically active form for periods in excess of 100 days as measured by direct assays. . . . The eventual clinical application of these polymers for delivery of macromolecules such as insulin, heparin, or enzymes may merit consideration.").

Langer & Folkman II: p. 798-99 ("Polyvinylalcohol, Hydron and ethylene-vinyl acetate copolymer were examined for the ability to release soybean trypsin inhibitor . . .") ("These studies show that sustained release of proteins and other macromolecules from polymeric vehicles can be achieved over prolonged periods.").

Langer VIII: p. 1 ("One approach that has received increasing attention as a means of prolonging drug release has been the incorporation of drugs in solid polymers (e.g. silicone rubber, ethylene-vinyl acetate copolymer). This method permits drugs to be released for long time periods in a *controlled* fashion."); p. 10 ("Controlled-release polymer formulations may also find applications in other clinical areas. One such area that has received increasing attention is the controlled release of antibiotics. . . . Polymers have also been used to deliver anesthetics, anti-malarial drugs, anticoagulants, and drugs to combat cardiac arrhythmia."); p. 27 ("However, several recent studies have demonstrated that matrix systems can be engineered to permit

continuous release of large molecules. By solvent casting normally impermeable polymers such as ethylene-vinyl acetate copolymer in volatile solvents . . . along with powdered macromolecule, a series of interconnecting channels is formed within the polymer matrix. . . . These macromolecular delivery systems now open the possibility of delivering many important large molecular weight compounds such as insulin or interferon for prolonged periods."); Fig. 20; p. 28-29 ("[T]he volume of bioerodible systems becomes smaller with time, and, as the polymer surrounding the drug is eroded, the drug escapes."); p. 30 ("Erosion could be caused by hydrolytic or enzymatic cleavage of the crosslinks so that the ultimate degradation products are high molecular weight polymers. Alternatively, the degradation could occur in the polymer backbone so that the degradation products have low molecular weights."); p. 31-32 ("The third category of biodegradable systems are water-insoluble polymers that undergo hydrolytic or enzymatic backbone cleavage and are solubilized to small water-soluble molecules. . . . The best example of this class of polymer is polylactic acid or copolymers of lactic acid and glycolic acid."); p. 32 ("Sidman and coworkers . . . developed a peptide copolymer of glutamic acid and ethyl-*L*-glutamate."); p. 32-34 ("Pendant Chain Systems: In this type of system, a drug is chemically bound to a polymer backbone and is released by hydrolytic or enzymatic cleavage. The use of these therapeutic agents has received considerable attention in drug-related research. The major thrust so far has been the design of polymer-drug complexes for short-term use that can reduce toxicity, increase therapeutic efficiency, or be targeted towards specific cells or organs. . . . The drug itself can be attached directly to the polymer or it can be attached via a spacer group. The spacer group may be used to affect the rate of release and the hydrophilicity of the system. . . . To achieve near constant release, the cleavage of the drug from the polymer must be the rate-limiting step."); Fig. 22.

Langer & Folkman III: p. 114-15; p.117-18 ("Demonstration of Long-term Release") ("In initial trials with soybean trypsin inhibitor . . . protein was released . . . least rapidly from ethylene-vinylacetate copolymer."); p. 119-20 ("When tested in this fashion, ethylene-vinylacetate copolymer pellets continued to produce zones on these slides for over 100 days, indicating that the pellets were releasing nearly 1 ug/day or biochemically active protein."); p. 123-25 ("Insulin Delivery"); p. 125-26 ("Immunization Procedures").

Rhine: p. 265 ("Matrixes composed of ethylene-vinyl acetate copolymers are useful vehicles for the sustained release of macromolecules such as proteins These polymer systems had uniform drug distribution, and their release kinetics were reproducible."); p. 267 ("Therefore, macromolecules were added to a solution of polymer dissolved in a volatile solvent (methylene chloride). This mixture, when cast and dried, produced matrixes capable of sustained macromolecular release. . . . The reproducibility of release kinetics for matrixes prepared by low temperature methods was demonstrated for different proteins and for a range of particle sizes and loadings."); p. 268 ("A coating can also be used to control macromolecular release kinetics."); p. 269 ("Clinically, these systems may prove valuable as single-step methods for immunization or for the continuous delivery of insulin and other high molecular weight drugs.").

Aebischer: p. 282-83 ("Chemically inert polymer matrices, allowing controlled release of entrapped macromolecules over long time periods . . . open a new avenue of investigation. . . . The solvents used appear to have no detrimental effects on the biological activity of a number of

growth factors."); p. 283 ("Channel Fabrication"); p. 283 (disclosing the use of an impermeable outer coating which results in directional release of the treating factors into the lumen of the device); Table 1; p.286 ("The present study demonstrates that ethylene vinyl acetate copolymer can be fabricated into tubes with adequate physical properties for nerve entubulation and allows the controlled release of macromolecules.").

Langer IX: p.267 ("Two polymers suitable for sustained macromolecular release, poly(hydroxyethyl methacrylate), and alcohol-washed ethylene-vinyl acetate copolymer, were noninflammatory.") ("[W]e provide documentation that two polymers suitable for sustained macromolecular release, poly(hydroxyethyl methacrylate) (polyHEMA) and alcohol-washed ethylene-vinyl acetate copolymer, possess a high degree of biocompatibility in the rabbit cornea."); p.269; Table 1; p.276.

Langer X: p.179-80 ("Although we investigated several polymeric systems, the best results from the standpoint of tissue biocompatibility and long-term release (>100 days) were obtained with ethylene-vinyl acetate copolymer."); p.180 ("Biocompatibility studies"); p.181-87 ("In vitro and in vivo release kinetics"); p.192 ("Possible mechanisms of release of macromolecules") ("The absence of effect of ionic strength (fig7) suggests that osmotic pressure or charge interactions of drug with polymer have negligible roles in affecting release rates."); p. 195-200 ("Here, four studies exploring biomedical uses of these polymer systems are discussed. These include: (1) insulin delivery systems, (2) vehicles for immunization, (3) interferon delivery systems, and (4) systems for delivering anticancer or antiangiogenic macromolecules.").

Langer XI: p.95-96 ("Recent studies in our laboratory have demonstrated, however, that solvent casting of a variety of polymeric materials (ethylene-vinyl acetate copolymer, polyvinylalcohol, poly-2-hydroxymethyl-methacrylate) in the presence of powdered drug permits continuous release of macromolecules for over 100 days.").

Brown: p.1181 ("Macromolecules such as enzymes, antigens, and insulin have been released in biologically active form [from ethylene-vinyl acetate copolymers] for up to 6 months *in vivo*."); p. 1184 ("These data show that *in vivo* release can be accounted for by the same mechanisms operating *in vitro*; this should now make possible the further development and increased use of ethylene-vinyl acetate copolymer drug delivery systems.").

Kost & Langer: p.47-48 ("Bioerodible controlled systems."); p.48-49 ("Applications").

Hsu & Langer: p. 445-46 ("The current study shows the MW of EVAc copolymer is as important as drug loading and drug particle size in affecting the drug release kinetics. A release mechanism, which includes the properties of the polymer carrier, is proposed to serve as a guideline in selecting a suitable EVAc polymer carrier for a particular drug release device."); p.459.

Bawa: p.259 ("For example, EVAc polymers have been used as . . . delivery systems for insulin, interferon, and antigens."); p.263 ("Minimal effects exist due to osmosis or charge interaction of the drug with the polymer."); p.266 ("The data should be useful in the design of release vehicles for various polypeptides, polysaccharides, and other bioactive agents now produced by genetic engineering.").

Leong & Langer: p.202; p.203 ("The two common chemically controlled systems are a biodegradable matrix in which the drug is dispersed, and a polymer-drug conjugate in which the drug molecules are linked to the side chains of the polymer."); p.206-209 (describing use of biodegradable polymers for contraceptive systems); p.210-11 ("Against Ehrlich ascites carcinoma in rats, a sustained release of 5-fluorouracil from poly(ethylenevinylalcohol) is more efficacious than free drug administration."); p.211-14 ("Pendant systems"); p. 214-15 (use of EVAc for hormonal therapy and angiogenesis inhibition); 219-23 ("The clear demonstration of the feasibility [of sustained release of insulin from polymer] was later provided by a study using poly(ethylenevinylacetate) (EVAc).").

Baker: p.14-15 ("Diffusion-Controlled Monolithic Systems"); p.15-16 ("Biodegradable Systems"); 161-65 ("Poly(ethylene vinyl acetate)").

Langer XII: p.162 ("In chemically controlled systems, release is accomplished either by biodegradation of the polymer or by chemical cleavage of the drug from a polymer backbone on which the drug had been bound as a pendent group."); p.163 ("A variety of reservoir and matrix devices are prepared from swollen crosslinked hydrophilic polymers (hydrogels). Most successful devices of this kind are based on poly (2-hydroxyethyl methacrylate) (HEMA) and related polymers although hydrophilic homopolymers of (poly vinyl 1-2-purrolidone) (PNVP), poly (vinyl alcohol) (PVA) and copolymers thereof have been tested with considerable success.") ("Ethylene-vinyl acetate (EVA) copolymers are prepared by emulsion copolymerization of ethylene and vinyl acetate. They are soluble in organic solvents and they can be used to prepare films or rods of dimensional stability and good mechanical strength."); p. 163-64 ("Biodegradable Polymers"); 164-67 (clinical uses for controlled-release polymer systems).

Langer XIII: p.166; p.170 ("Studies have also been conducted to explore numerous applications of these systems. These include release of insulin . . . , anti-calcification agents . . . , interferons . . . , growth factors . . . and inhibitors . . . , and neurologically active agents.").

Chasin: p.43-44 ("In designing a biodegradable system that would erode in a controlled heterogeneous manner without requiring any additives, we have suggested that due to the high liability of the anhydride linkage, polyanhydrides may be promising candidates."); p.45 ("Molding procedures"); p.47-62 ("Kinetics of Drug Release") (describing release of various compounds); p.66-68 (polyanhydride safety and clinical studies).

Langer XIV: p.538-40 (describing polymers used in controlled release systems, including cellulose, poly(glycolic acid) and poly(lactic acid), poly(ortho esters), polyanhydrides, silicone rubber, ethylene-vinyl acetate copolymer, and poly(2-hydroxyethyl methacrylate)); 540-42 (describing clinical uses for controlled release systems).

Brem: p.2 ("The ethylene-vinyl acetate copolymer (EVAc) is an example of a non-biodegradable polymer while poly[bis(p-carboxyphenoxy) propane-sebacic acid] copolymer (PCPP-SA) and the fatty acid dimmer-sebacic acid copolymer (FAD-SA) are examples of biodegradable polymers."); p.3 ("Clinical applications for the EVAc polymer include drug delivery for contraception, insulin therapy, cancer chemotherapy, glaucoma treatment, dental caries prevention, and asthma therapy."); p.4-6 (describing in vivo and clinical studies of PCPP-SA and EVAc based delivery of chemotherapeutic drugs).

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Langer XV: p.102 ("Our best long-term release results were obtained with relatively hydrophobic polymers, such as ethylene-vinyl acetate co-polymer or lactic glycolic acid copolymer, using methylene chloride as a casting solvent."); p.105 ("Therefore, we proposed to initiate studies on the development of a new class of bioerodible polymers: polyanhydrides."); p. 109 ("Through the NH₂ groups of lysine, specific amino acid sequences such as arginine-lysine-aspartic acid (RGD) have been chemically coupled to polylactic acid-co-lysine.").

Thompson: p.31-32; p.32 ("In this article, we include hydrolysis and enzymatic degradation under the heading of biodegradative processes."); p. 32-33 ("Collagen is one of the most widely used and best characterized of the natural biomaterials"); p.33 ("Gelatin, cross-linked with formaldehyde, has been studied in vitro as a drug delivery matrix . . ."); p.33-34 ("Starch"); p. 34 ("Furthermore, because of its hydrophilicity, cellulose has been utilized in pharmaceutical formulations to enhance water uptake and improve drug delivery.") ("The degradation of synthetic polymers is, in general, brought about by simply hydrolysis, although in some cases enzymatic processes assist in the degradation mechanism."); p.35 ("Since . . . the degradation characteristics of [poly(glycolic acid)] are predictable and reproducible, PGA has become a material of choice for many proposed applications calling for a synthetic biodegradable polymer.") ("Poly(L-lactic acid)"); p. 36 ("Poly (ε-caprolactone)") ("[Poly(orthoesters)] have therefore been exploited as constant rate drug delivery devices.") ("Poly(anhydrides)"); p.36-41 ("Hydrophobic polymers") ("Poly(ethylene)"); p. 41-44 ("Hydrophilic Polymers") ("Poly(2-hydroxyethyl methacrylate)"); p.44 ("Natural and synthetic biodegradable polymers have been utilized in drug delivery and tissue engineering. Drug delivery systems based on biodegradable polymers facilitate the controlled release of drugs with the concurrent degradation of the polymer.").

Chandrasekaran: p.587 ("The simplest to a bioerodible drug delivery system is to disperse or dissolve the drug in a water-soluble polymer, which will slowly erode in an aqueous medium Another approach involves the synthesis of hydrophobic water-insoluble polymers in which the major fraction of the drug is released by erosion of the polymer matrix . . ."); p.588 ("Hydrophobic polymer solubilization can be achieved as a result of a chemical reaction that takes place at either a pendant group of the polymer or within the polymer backbone. When the reaction is confined to the pendant group, no backbone cleavage takes place, and one of the reaction products is a hydrolytically stable water-soluble polymer. . . . Hydrophobic polymers can also be solubilized by an ionization reaction of pendant carboxyl groups; drug dissolution and release rate kinetics are obtained from partially esterified copolymers derived from ethylene-maleic anhydride or methyl vinyl ester-maleic anhydride.").

Kim: p194-96; Fig.4; 197-201 ("Drug Diffusion through Polymers"); p.202-204 ("Release Rate from Monolithic Devices"); p.204-206 ("Mechanistic Considerations of Drug Diffusion through Polymer Membranes"); p.215-220 ("Hydrophobic Polymers as Drug Carriers") ("Ethylene-Vinyl Acetate Copolymer (EVA)"); p.220-23 ("The synthesis of biodegradable polymers for controlled drug release is based on different strategies. 1. A degradable polymer medium to which a drug is dispersed. Here drug diffusion through the polymer matrix is influenced by the degradation of the polymeric material. 2. A degradable polymer medium to which a drug is attached through a hydrolytically labile linkage. Drug release is controlled by both hydrolysis of the drug from the polymer and by diffusion of the

drug through the polymer matrix."); p.226-28 ("Design of Chemically Bound Polymer-Bioactive Agent (PBA) Systems"); p.228-29 ("Models of Chemically Bound Polymer-Bioactive Agent Systems."); p.229-46 ("Examples of Chemically Bound Polymer-Bioactive Agent Systems").

Dev: Abstract; p. 273 ("The purpose of this study was twofold: first, to test a polymer-coated removable stent system for local delivery of two lipid soluble drugs . . . and second, to compare these two drugs with respect to kinetics of their delivery to the arterial wall with the stent in place and their tissue washout rates after removal of the stent."), ("We used a commercially available biomedical grade polyurethane [as a stent coating]. . . . To study the kinetics of drug delivery, we used two lipid soluble compounds: forskolin and etretinate."), ("Ratio of peak drug levels in the vessel wall to those in the blood was 6,000 for etretinate and 780 for forskolin. . . . Polymer-coated stents could be used for local drug delivery to the vessel wall."); p. 274-75 ("the drug levels [of etretinate] in blood and the distant tissues are extremely low, and the ratio of local to systemic drug levels is very high (~6,000); p. 277 ("This [preferential release of drug into the arterial wall] may reflect slower diffusion of etretinate in the aqueous medium than forskolin or presence of significant tissue binding of etretinate.").

Claim 8 [8F] (cont'd): the device being flexible in three dimensions by manipulation by human hands,

Where Found in the Prior References:

Peterson '166: Col. 2:51-54 ("Typical polymeric carriers are polyesters, polyamides, polyurethanes and other condensations polymers . . .").

Schwartz '823: Abstract ("A radially expandable stent . . . the cylindrical body comprising a plurality of metal elements joined to allow flexing of the cylindrical body along the longitudinal axis of the body whereby the stent can conform to a curved body lumen . . ."); col. 1:9-14; col. 1:17-19; col. 1:53-55; col. 2:16-19 ("It is therefore an object of the present invention to provide a stent having longitudinal flexibility which allows it to conform to curves and variation in body lumens."); col. 2:29-40; col. 2:44-49; col. 3:48-57; col. 3:58-64 ("The improvement of the present invention includes applying to the above-mentioned type of stent a flexible or elastomeric polymeric film which extends between the metal elements."); col. 4:20-27 ("The term 'film' or 'flexible film' herein therefore means that, as applied to the metal stent elements in a thin cross section, the film is capable of flexing or stretching to preserve the radial expandability and axial flexibility of the implanted stent."); col. 4:49-5:41 ("It also produces a stent having a flexible film which extends between the metal elements of the stent and which will not significantly affect the ability of the stent to conform to curved body lumens. . . . A suitable crimping tool . . . may be used to tighten the stent over the balloon. A manual operation of sequentially squeezing the stent over the balloon is also acceptable."); col. 5:65-6:1; col. 6:17-20; col. 6:30-32; col. 6:43-47; col. 6:49-52; col. 6:58-68; col. 8:19-41.

Scott '928: Col. 8:23-60 (disclosing use of EVA).

Tartaglia '113: Abstract; col. 1:15-19 ("Ideally, implantation of such stent is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:57-60 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member."); col. 1:64-67 ("The polymer material can be a thermoplastic or an elastomer, for example, so that the film can stretch or deform radially when the stent structural member is expanded."); col. 2:23-33; col. 2:48-55; col. 5:6-10; col. 6:54-56; col. 7:18-21 ("The apertures also improve the flexibility of the polymeric material, allowing the stent segment to be more easily rolled and uncoiled during expansion of the stent structural member . . ."); col. 10:40-47.

Wolff '208: Col. 2:7-9 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 9:39-42 ("The device is fixed into place either by radial expansion in devices such as shown in Fig. 1 or are deformed by a balloon catheter in the case of devices in accordance with Fig. 2."); col. 10:3-45 ("The stents are arranged on the distal end of the catheter such that the catheter can provide remote, transluminal deployment of the stents, with the metal stent inside the polymeric stent, from an entry point into a selected portion of the body lumen to be treated and also remote actuation of an expansion mechanism from the proximal end of the catheter. The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen."); col. 10:51-57; col. 10:66-11:3 ("The metal stent is crimped onto the balloon and includes an elongated lead extending to the proximal end of the catheter assembly where it includes an enlarged portion to enable an operator to securely grip the lead."); col. 12:1-15.

Berg '354: Page 2:14-15 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen."); p.3:18-22 ("The transluminal delivery can be accomplished by a catheter designed for the delivery of stents and the radial expansion can be accomplished by balloon expansion of the stent, by self-expansion of the stent, or a combination of self-expansion and balloon expansion. Thus the present invention provides a stent which may be delivered and expanded in a selected blood vessel without losing a therapeutically significant amount of a drug applied thereto."); p. 5:28-29.

Buscemi '450: Col. 1:58-60; col. 7:10-20 (" . . . said tubular main body including a slot extending lengthwise through the main body and defined by opposing edges of the main body wherein the opposing edges must be moved toward each other under compression in order to transport the biodegradable stent through a vessel of a living being . . ."); col. 8:18-24.

Ding '536: Col. 1:48-51 ("One type of self-expanding stent has a flexible tubular body formed of several individual flexible thread elements each of which extends in a helix configuration with the centerline of the body serving as a common axis."); col. 3:5-9; col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 3:56-64 ("... the tubular body is formed of a self-expanding open braid of fine, single or polyfilament metal wire which flexes without collapsing, readily axially deforms to an elongate shape for transluminal insertion via a vascular catheter and resiliently expands toward predetermined stable dimensions upon removal in situ.").

Dinh '227: Col. 1:32-35 ("The stent is typically inserted by catheter into a vascular lumen told [sic] expanded into contact with the diseased portion of the arterial wall, thereby providing mechanical support for the lumen."); col. 2:62-66 ("The inclusion of a polymer in intimate contact with a drug on the underlying stent structure allows the drug to be retained on the stent in a resilient matrix during expansion of the stent and also slows the administration of drug following implantation."); col. 3:14-22; col. 6:62-67; col. 7:13-21; col. 8:29-43 ("For example, a deformable metal wire stent such as that disclosed in U.S. Pat. No. 4,886,062 issued to Wiktor could be coated with fibrin as set forth above The stent and fibrin would could then be placed onto the balloon at a distal end of a balloon catheter and delivered by conventional percutaneous means . . . to the site of the restriction or closure to be treated where it would then be expanded into contact with the body lumen by inflating the balloon."); col. 8:49-52 ("A catheter has a balloon upon which a stent has been placed, the stent having a deformable metal portion and a fibrin coating, thereon."); col. 8:64-9:2; col. 9:18-24; col. 9:49-50 ("The resulting fibrin stent includes the stent embedded in a very thin elastic film of fibrin."); col. 9:59-63; col. 12:24-28.

Domb '055: Abstract ("Preferred embodiments include catheters, tubes, and implants that abut tissue following implantation into the body . . ."); col. 4:25-32; col. 5:27-37 ("In a particularly preferred embodiment, polymers incorporating steroids are coated onto devices including tracheal T-tubes, stoma stents, laryngeal/bronchial stents, laryngeal keels, and nasogastric tubes."); col. 5:46-54; col. 5:60-62; col. 7:10-20; col. 7:40-52; col. 9:15-30; col. 9:55-10:2; col. 10:21-52; col. 10:60-11:11.

Fox '096: Col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages.").

Hunter '981: Col. 16:31-56; col. 17:63-18:7 ("[T]he anti-angiogenic compositions of the present invention may be formed as a film. . . . Such films are preferably flexible with a good tensile strength . . . and has controlled permeability."); col. 22:3-7; col. 22:21-39; col. 22:54-58; col. 23:26-30; col. 60:35-45; Fig. 17E; col. 66:13-22 ("As discussed above, sterile, pliable, stretchable drug-polymer compounds (e.g., films) may be utilized in accordance with the

methods described herein in order to isolate normal surrounding tissues from malignant tissue during resection of cancer.").

Kowligi '782: Col. 4:28-37.

Lambert '922: Col. 3:54-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected.)"); col. 8:1-6.

Lambert '308: Page 6:21-28 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected.)").

Myler '563: Abstract ("When elongated in an axial direction, the stent is reduced in cross-sectional area."); col. 2:13-16 ("The stent is configured to permit radial expansion, such as under the force generated by balloon dilation, and radial contraction in response to axial elongation."); col. 2:22-26; col. 2:27-28; col. 3:13-15; col. 3:33-34; col. 3:44-46; col. 3:48-51 ("Alternatively, tubular stents formed from flexible non-metal materials such as elastomeric polymers or rubber (latex) can also be radially reduced by axial elongation in accordance with the present invention."); col. 3:58-61; col. 4:9-12; col. 4:30-43 ("Suitable envelope materials include elastic materials such as latex and others that can be readily selected by one of skill in the art. . . . In general, biocompatible materials which can tolerate expansion of the stent between the insertion diameter and expanded diameter can be used."); col. 5:1-16; col. 5:50-54; col. 6:18-23; col. 10:12-14 ("The balloon is inflated, thereby expanding the stent radially outwardly until it contacts either a previously dilated, or presently stenosed wall."); col. 11:55-58; col. 11:63-65; col. 12:11-13; col. 12:19-23; col. 12:63-13:1 ("Suitable coating materials include elastic materials such as polyethylene or PET or other materials that can be readily selected by one of skill in the art. In general, any biocompatible material which can tolerate expansion of the stent between the insertion diameter and treatment diameter can be used."); col. 13:61-66; col. 19:18-30; col. 19:65-20:7; col. 20:51-57.

Palmaz '417: Abstract ("A plurality of expandable and deformable intraliminal vascular grafts are expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 1:17-23 ("The invention relates to an expandable intraliminal graft for use within a body passageway or duct and, more particularly, expandable intraliminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease; and a method and apparatus for implanting expandable intraliminal grafts."); col. 3:56-4:7; col. 4:28-37; col. 5:4-5:20 ("The present invention includes: a plurality of expandable and deformable, thin-walled tubular prostheses . . ."); col. 5:41-43; Fig. 10; Fig. 9; col. 6:6-9; col. 6:20-22; col. 6:63-7:2; col. 7:64-8:2; col. 8:36-60; col. 10:6-14; col. 10:55-58 ("Disposed between adjacent tubular members, or adjacent grafts, or prostheses, is at least one connector member to flexibly connect adjacent tubular members, or grafts, or

prosthesis."); col. 12:19-21; col. 12:33-38; col. 12:41-63 ("As seen in Fig. 9, because of the disposition of flexible connector members between adjacent tubular members 71, or grafts, or prostheses 70, graft, or prosthesis 70' is able to flexible bend or articulate, with respect to the longitudinal axis of graft, or prosthesis, 70', so as to be able to negotiate the curves or bends found in body passageways. . . . It should be noted that connector members permit the bending, or articulation, of adjacent tubular members in any direction about the longitudinal axis of graft, or prosthesis."); col. 12:64-66; Fig. 10; col. 12:66-13:2; col. 13:22-24; col. 13:31-40; col. 14:17-19; col. 14:27-29; col. 14:41-43; col. 14:48-59; col. 15:18-30; col. 15:33-40; col. 15:61-63; col. 15:67-16:6; col. 16:20-29; col. 16:34-37; col. 16:45-54; col. 16: 59-67.

Aebischer '486: Col. 3:56-63.

Schiraldi '243: Col. 1:8-21 ("The extruded film drug delivery system of the present invention, which has incorporated therein the medicament to be dispensed, is so thin and flexible when wet as to be unobtrusive to the patient after it has been properly positioned and placed in the mouth."); col. 2:30-51.

Valentini '029: Col. 1:56-2:4; col. 2:29-41 ("The devices can be formed from various polymeric materials, such as acrylic copolymers, polyvinylidene fluoride or polyurethane isocyanate, adapted to receive the ends of the severed or otherwise damaged nerve."); col. 3:62-67 ("The sheet is then wrapped around the nerve segments and the resulting tube is closed by further sutures, adhesives or friction."); col. 4:46-59 (disclosing use of flexible polymeric materials).

Wood '066: Abstract; col. 2:56-3:17; col. 7:51-65; col. 17:19-22; col. 17:30-34 (" . . . to give a flexible, elastomeric, white cryogel membrane . . ."); col. 18:1-4; col. 18:13-16; col. 18:26-30.

Strecker '746: Abstract ("An endoprosthesis in the form of an elongated hollow structure . . . once correctly positioned will expand from an initial state with a narrow lumen into a state with a lumen that is as wide as its placement will allow. It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen."); col. 1:12-22 ("Once correctly positioned it will expand from an initial state with a narrow lumen into a state with a lumen that is as wide as its placement will allow. . . . The lumens can be expanded by mechanically stretching them with a known balloon catheter. They can also be compressed prior to implantation and stretch out on their own subject to the resilience introduced by the compression."); col. 1:63-2:2; col. 2:21-32; col. 2:33-38; col. 2:65-3:4; col. 6:30-32; col. 7:16-35; col. 8:19-10:19.

Lambert '246: Col. 3:55-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected.)").

Bellamkonda '029: Col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making

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same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 4:48-57; col. 10:32-40; col. 11:33-40.

Dayton '382: Abstract ("The device comprises a stent which is formed from metal or polymers into a predetermined shape which includes a plurality of holes . . . to provide a desired bending modulus."); col. 3:62-4:12; col. 4:42-50; col. 4:54-5:3; col. 8:42-59.

Burt '036: p.14:9-27; p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size.").

Goldin '568: Col. 1:55-62 ("Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:8-12; col. 2:24-29 ("Microporous membranes for release of proteins by controlled diffusion have been fabricated from ethylene vinyl acetate (EVA) . . .").

Palmaz '665: Abstract ("An expandable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 1:11-17; col. 3:3-7; col. 3:33-39; col. 4:1-6; col. 4:33-36; col. 6:4-11; col. 7:20-25.

Palmaz '762: Abstract ("An expandable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 3: 45-51 ("...upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular shaped member may be expanded and deformed to expand the lumen of the body passageway."); col. 4: 14-19; col. 4: 43-46; col. 5: 43-45; col. 6: 18-24; col. 8: 7-21.

Palmaz '337: Abstract ("An expandable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 3: 37-44 ("... and the tubular shaped member having a second, expanded diameter, upon the application from the interior of the tubular shaped member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular shaped member, whereby the tubular shaped member may be expanded to expand the lumen of the body passageway."); col. 3:60-4:2 ("The method of the present invention comprises the steps of: ... and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded, ..."); col. 8: 17-22.

Zaffaroni '254: Col. 7: 5-8 ("Device 10 is capable of being substantially straightened by passing through a hollow instrument for positioning it in the uterus 25.").

Aebischer: p. 284 (disclosing manipulation of polymer tube to allow entry of nerve stumps).

Dev: p. 273 ("We used a commercially available biomedical grade polyurethane Tecoflex is a biocompatible, flexible, and an elastic membrane-forming polymer.").

Claim 8 [8G] (cont'd): the device being capable of restricting the through passage of at least one type of macromolecule therethrough,

Where Found in the Prior References:

Schwartz '823: Abstract; col. 2:29-40; col. 2:49-53; col. 3:58-61 ("The improvement of the present invention includes applying to the above-mentioned type of stent a flexible or elastomeric polymeric film which extends between the metal elements."); col. 3:64-4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof."); col. 6:17-20; col. 7:25-8:11.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); Fig. 3; col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-33; col. 5:34-6:29; col. 6:37-41; col. 6:41-45 ("Modifications of the polymer coating include a ring that encompasses the proximal portion of the stent, single or multiple strips that cover a portion of the stent, or a polymer coating with perforations."); col. 8:23-25 ("Ethylene vinyl acetate copolymer (EVA) (Catalog #34,691-8) was obtained from Aldrich Chemical Company, Inc. (Milwaukee, Wis.); col. 10:24-33; col. 12:1-6; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow Controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Col. 1:7-10 ("This invention relates generally to expandable intraliminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 1:64-2:2 ("The polymer material can be a thermoplastic or an elastomer, for example, so that the film can stretch or deform radially when the stent structural member is expanded. The film of polymer material can be formed as a solid sheet, or can incorporate holes of various sizes and shapes to promote rapid endothelialization."); col. 4:15-24; col. 4:25-46; col. 4:47-5:3; col. 5:4-9; col. 5:49- 6:25 ("The polymeric material is preferably selected from thermoplastic and elastomeric polymers. . . . In another currently preferred embodiment, the polymeric material can be ethylene vinyl acetate (EVA) . . ."); col. 6:26-65; col. 7:23-42; col. 7:63-65; col. 8:12-57; col. 9:5-12; col. 10:12-30.

Wolff '208: Col. 2:7-16 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:28-30 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 6:59-62 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously. The polymer may be biostable or bioabsorbable. If biostable, the drug would diffuse out of the polymer."); col. 6:64-67; col. 7:59-61; col. 9:23-33 ("That layer may be a simple barrier which limits diffusion of drugs in the polymer. In that event, the smaller molecules could elute out immediately, while larger compounds would not elute until later when the layer has biodegraded."); col. 12:37-40 ("8. The device of claim 1 also comprising a barrier coating of polymeric material on the drug-containing filament to limit the rate of drug elution.").

Berg '354: Page 2:43-54 ("Viewed from a further aspect the invention provides the use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug-eluting surface coating."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:29-31 ("Also, stents made with biostable or bioabsorbable polymers such as poly(ethylene terephthalate), polyacetal, poly(lactic acid), poly(ethylene

oxide)/poly(butylene terephthalate) copolymer could be used in the present invention. "); Table 1; p. 4:5-24; p. 6:6-11; p. 6:15; p. 6:24-35; p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Abstract ("A stent made of biodegradable material includes a drug that is released at a rate controlled by the rate of degradation of the biodegradable material."); col. 2:16-17; col. 4:1-5 ("In one embodiment, the main body includes a film that is preferable combined with the plurality of fibers disposed around the main body. The film combined with the plurality of fibers defines the outer surface of the main body."); col. 4:15-16 ("Preferable, the main body of the stent includes a film covering the inner surface."); col. 4:19-22.

Ding '536: Abstract ("The coating includes a relatively thin layer of biostable elastomeric material containing an amount of biologically active material, particularly heparin, dispersed in the coating in combination with a non-thrombogenic surface."); col. 1:24-29 ("The present invention relates generally to providing biostable elastomeric coatings on the surfaces of implants which incorporate biologically active species having controlled release characteristics in the coating particularly to providing a non-thrombogenic surface during and after timed release of the biologically active species."); col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 5:10-56 ("Polymers generally suitable for the undercoats or underlayers include silicones (e.g., polysiloxanes and substituted polysiloxanes), polyurethanes, thermoplastic elastomers in general, ethylene vinyl acetate copolymers, polyolefin elastomers, polyamide elastomers, and EPDM rubbers. The above-referenced materials are considered hydrophobic with respect to the contemplated environment of the invention."); col. 12:62-13:2; col. 13:13-26; col. 13:37-40; col. 14:5-17; col. 14:22-34.

Dinh '227: Col. 2:51-54 ("To accomplish this while not affecting the strength of the overall fibrin stent structure, a first layer is applied to a stent body, the first layer incorporating a polymer and the therapeutic substance."); col. 2:62-66 ("The inclusion of a polymer in intimate contact with a drug on the underlying stent structure allows the drug to be retained on the stent in a resilient matrix during expansion of the stent and also slows the administration of drug following implantation."); col. 3:10-14; col. 3:25-38; col. 5:3-7; col. 5:44-55; col. 5:56-57; col. 6:13-19 ("In U.S. Pat. No. 4,548,736 issued to Muller et al., a dense fibrin composition is disclosed which can be a bioabsorbable matrix for delivery of drugs to a patient. Such a fibrin composition can also be used in the present invention by incorporating a drug or other therapeutic substance useful in diagnosis or treatment of body lumens to the fibrin provided on the stent."); 6:50-56 ("Alternatively . . . a dense fibrin composition suitable for drug delivery can be made without the use of microcapsules by adding the drug directly to the fibrin followed by compression of the fibrin into a sufficiently dense matrix that a desired elution rate for the drug is achieved."); col. 6:62-67; col. 7:10-13; col. 7:56-64 ("In another embodiment of the invention, the coating of polymer and drug on the stent is achieved by forming a first fibrin layer on the stent body which incorporates the therapeutic substance and then applying a second layer of

fibrin."); col. 8:52-60 ("Fig. 2 shows an alternative stent in which a fibrin film has been affixed to the underlying metallic framework by affixing it to the stent . . ."); col. 8:64-9:3; col. 12:24-28; col. 12:38-50.

Domb '055: Abstract ("Devices are provided having a polymer coating incorporating compounds inhibiting inflammation and infection, along with subsequent tissue growth onto and around the device. . . . Preferred polymeric coating are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); col. 1:12-15 ("This invention relates to invasive medical devices for delayed/sustained release of pharmaceutical compositions from a polymer that is coated or incorporated into the devices."); col. 3:54-57 ("In the preferred embodiments, these have utilized bioerodible polymers as the matrix for the drug to be released, usually as a function of diffusion and erosion of the polymer."); col. 4:22-36; col. 5:24-37; col. 5:41-45; col. 5:48-6:1; col. 6:24-26 ("Examples of suitable polymers include ethylene vinyl acetate, polyurethane, silicones, hydrogels, polyurethane, and polyvinyl chloride."); col. 7:10-20; col. 7:40-52; col. 9:15-30; col. 9:55-10:2; col. 10:21-52; col. 10:60-11:11; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 11:36-38 ("The medical device of claim 1, wherein the polymer is selected from the group consisting of polyurethane, ethylene vinyl acetate, silicones, hydrogels, and polyvinyl chloride."); col. 11:39-44; col. 12:11-22; col. 12:23-25; col. 12:26-31; col. 12:32-42.

Fox '096: Abstract ("A method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers, and antimicrobial agents . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 2:48-65; col. 3:55-67 ("The polymeric coating agent component of the coating vehicle of the present invention is selected from the group consisting of biomedical polyurethanes, biomedical silicones, biodegradable polymers and combinations thereof."); col. 19:11-16; col. 31:62-64.

Hunter '981: Col. 1:12-17; col. 3:42-45 ("Within one aspect of the present invention, compositions are provided (anti-angiogenic compositions) comprising (a) an anti-angiogenic factor and (b) a polymeric carrier."); col. 3:53-61; col. 12:23-25 ("As noted above, the present invention provides compositions comprising an anti-angiogenic factor, and a polymeric carrier."); col. 16:31-56; col. 17:63-18:7 ("[T]he anti-angiogenic compositions of the present invention may be formed as a film. . . . Such films are preferably flexible with a good tensile

strength . . . and has controlled permeability."); col. 22:3-7; col. 22:54-58; col. 47:58-49:7; col. 52:4-8; col. 69:19-62; col. 84:62-86:24; 86:56-59; col. 87:11-22; col. 88:19-26.

Kowligi '782: Abstract ("The elastomeric coating is made of polyurethane or another biocompatible non-porous elastomers and precludes tissue ingrowth into the outer cylindrical wall, minimizes suture hold bleeding, and increases suture retention strength, while reducing the incidence of serous weepage."); col. 1:18-26; col. 2:15-20; col. 2:38-47; col. 2:53-59; col. 3:27-37; Fig. 1; Fig. 2; Fig. 3; col. 2:60-67 ("PTFE tube 32 includes an inner cylindrical wall and an opposing outer cylindrical wall. As shown in Fig. 2, outer cylindrical wall 36 is coated entirely around its circumference by a uniformly thick coating of a biocompatible elastomer."); col. 3:27-38; col. 4:16-27 ("In regard to elastomeric coating 38 shown in Fig. 2, such elastomeric coating is selected to be a biocompatible elastomers and may be selected from the group consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 4:37-39 ("The elastomeric coating should also be sufficiently non-porous to preclude serous weepage and inhibit tissue ingrowth therethrough."); col. 5:4-7; col. 7:49-8:9; col. 8:38-44; col. 9:65-10:6; col. 10:18-24; col. 10:33-42; col. 10:43-50; col. 10:51-59; col. 10:60-67.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 2:16-35; col. 2:40-50; col. 3:8-12; col. 3:29-32; col. 3:33-49; col. 3:55-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); col. 7:29-32; col. 7:38-41; col. 10:57-64; col. 11:49-51; col. 11:65-12:13; col. 12:43-64; col. 13:13-19.

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p. 3:10-31 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); p. 4:2-12; p. 6:21-28 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); claim 1:1-14; claim 8:1-5; claim 10:1-3; claim 11:1-13; claim 22; claim 23:1-14; claim 19:4-31.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8.

Myler '563: Col. 2:10-13; col. 3:13-15; col. 3:52-54; col. 4:30-43 ("In a preferred embodiment, the interior and exterior walls of stent 10 are enclosed in a thin polymeric envelope. . . . Suitable envelope materials include elastic materials such as latex and others that can be readily selected by one of skill in the art."); col. 5:1-16; col. 5:39-41 ("For the above reasons, even the expanded pores for drug delivery should be small enough to maximize or prevent cell penetration, but large enough for drug delivery."); col. 12:11-13; col. 12:19-23; col. 12:28-33 ("Suitable materials include elastomeric polymers or natural rubber (latex). . . . Polymeric stents can be provided with relatively fluid impenetrable walls, or porous walls such as to allow drug delivery, as will be apparent to one of skill in the art."); col. 12:63-65 ("Suitable coating materials include elastic materials such as polyethylene or PET or other materials that can be readily selected by one of skill in the art."); col. 18:51-19:9; col. 19:18-30; col. 19:31-32; col. 19:61-63; col. 20:33-49; col. 20:51-57.

Palmaz '417: Col. 6:66-68; col. 11:3-14 ("Examples of a suitable biologically compatible coating would be porous polyurethane, Teflon™ or other conventional biologically inert plastic materials."); col. 11:26-31 ("Examples of biologically compatible coatings would include coatings made of absorbable polymers such as those used to manufacture absorbable sutures. Such absorbable polymers include polyglycoides, polyacoides, and copolymers thereof. ").

Tice '330: Col. 3:20-33 ("Suitable wall forming materials include polystyrene, ethylcellulose, cellulose acetate, hydroxyl propylmethylcellulose phthalate, cellulose acetate, dibutylaminohydroxypropyl ether, polyvinylbutyral, polyvinyl formal, poly(meth)acrylic acid ester, polyvinylacetal-diethylamino acetate, 2-methyl-5-vinyl pyridine methacrylate-methacrylic acid copolymer, polycarbonate, polyesters, polypropylene, vinylchloride-vinylacetate copolymer, polysaccharides, glycerol distearate, and the like. A preferred group of polymeric wall forming materials includes those which are biodegradable such as aliphatic polyesters including polylactide, polyglycolide, polycaprolactone and copolymers thereof."); col. 8:38-51.

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); col. 3:7-18; col. 3:56-63; col. 4:31-34 ("The outer membrane surface is nonporous, while porous inner membrane surface allows for the diffusion therethrough of active factor 26."); col. 5:18-28 ("In a preferred embodiment of the invention, the outer surface of the membrane is impermeable to solutes of any size, while the inner membrane surface contains pores [that] enable the active factors to diffuse out of the membrane and into the lumen of the channel."); col. 6:17-22 ("The layering procedure allows deposition of an impermeable coat on the outer surface of the device, insuring that the active factors incorporated into the membrane walls will be inhibited from diffusing through the external surface, and will diffuse only through the inner membrane surface into the lumen of the channel."); 6:54-61; col. 9:18-10:3.

Folkman '560: col. 2:43-68 ("A biocompatible plastically deformable polymer matrix . . . substantially impermeable to a macromolecule"); col. 3:18-23 ("The polymer matrixes, which are suitably used in the present invention, are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:36-51 ("Typical polymeric material suitable for forming the matrix . . . include . . . alkylene-vinyl acetate copolymers . . . crosslinked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:52-4:26 ("In the presently preferred embodiment the polymeric materials useful for forming the matrix are the ethylene vinyl ester copolymers of the general formula . . ."); col. 11:56-12:20.

Cohen '496: Col. 3:26-45 ("The polymer matrices . . . are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:65-4:39 ("In a presently preferred embodiment, the polymeric materials useful for forming the matrix are the ethylenevinyl ester copolymers of the general formula . . ."); col. 9:40-10:17; col. 10:18-32.

Schiraldi '243: Col. 1:8-21 ("The extruded film drug delivery system of the present invention, which has incorporated therein the medicament to be dispensed, is so thin and flexible when wet as to be unobtrusive to the patient after it has been properly positioned and placed in the mouth."); col. 1:58-60; col. 2:30-51; col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 9:36-55; col. 10:12-18.

Valentini '029: Abstract ("Medical devices employing semipermeable materials, such as acrylic copolymers, polyurethane isocyanate, and other biocompatible semipermeable polymers, are disclosed for use as guidance channels in regenerating nerves. . . . The guidance materials are chosen such that they are capable of allowing the diffusion of nutrients and other metabolites to the regenerating nerve site while excluding fibroblasts and other scar-forming cells."); col. 2:29-57 ("It has been discovered that the repair of severed or avulsed nerves can be greatly enhanced by the use of selectively permeable polymeric materials as nerve guidance channels. . . . The devices can be formed from various polymeric materials, such as acrylic copolymers, polyvinylidene fluoride or polyurethane isocyanate Preferable, the materials allow passage therethrough of solutes having a molecular weight of about 100,000 daltons or less. . . . The nerve guidance channels of the present invention are also preferably designed to retain nerve growth factors secreted at the anastomatic site or seeded therein, as well as retain any luminal matrix material placed inside the guidance channels."); col. 2:58-3:14; col. 4:46-59; col. 5:13-32 ("The success rate and quality of peripheral nerve regeneration was dramatically enhanced

through the use of a semipermeable material."); col. 5:42-6:12 ("The permselective characteristics of the inner membrane allow the exchange of nutrients, while concentrating growth factors released by the nerve and excluding scar-forming cells."); col. 6:14-24; col. 6:31-42.

Greco '135: Col. 3:48-4:1 ("These devices will consist of organic polymers and/or metallic materials including: . . . polyethylene . . . elastomeric organosilicon polymers, such as polysiloxanes, e.g. Silastic ®").

Aebischer '627: Col. 3:57-4:3 ("The polymeric insert includes pores having a molecular weight exclusion of from about 1 kD to about 1,000 kD, but preferably from about 25kD to about 100 kD."); col. 4:11-27 ("The terms 'semipermeable' is used herein to describe biocompatible membranes that allow the diffusion therethrough of molecules having a relatively low molecular weight, while excluding the passage of those having a relatively high molecular weight. . . . The semipermeable membrane can be made of various polymeric compositions such as polyvinylchloride, polyacrylonitrile, polyvinylidene fluoride, polystyrene, polymethylmethacrylate, polysulfone, and acrylic copolymers."); col. 7:57-8:14 ("In this embodiment, a semi-permeable membrane functions as a protective cell culture device for the neurotransmitter-secreting cells. The pores of the membrane should be large enough to enable the exchange of metabolites with body fluids, and to permit the diffusion therethrough of neurotransmitter produced by the cells therein, but are small enough to bar the passage therethrough of larger elements deleterious to the cells."); col. 13:31-48; col. 13:66-68; col. 14:1-2; col. 14:22-28; col. 14:54-56.

Wood '066: Abstract ("A controlled-release bandage containing therapeutic agents in a poly(vinyl alcohol) cryogel is disclosed. The bandage may include . . . hydrophobic particles to further insure controlled and constant release of therapeutic agents."); col. 2:56-66; col. 23:4-11.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:63-2:2; col. 2:12-15 ("The present invention on the other hand exploits a wrapping material that plastically deforms as it expands . . ."); col. 2:21-38; col. 2:59-64; col. 3:7-16; col. 3:27-33 ("The lining can to advantage be made of polymers or compounds thereof."); col. 3:51-62; col. 3:51-62; col. 5:49-54 ("The thread itself in an endoprosthesis of the type illustrated in Fig. 3 can also be wrapped in a coat of medicated and biodegradable wrapping material. . . . The prosthesis can of course alternatively be enclosed in a flexible-tubular coat."); col. 6:50-55; col. 6:59-62; col. 7:16-35; col. 8:4-8; col. 8:19-10:19.

Lambert '246: Abstract ("Thus, a polyurethane coating is applied to a prosthetic article, the coating then swelled . . . so that substantial quantities of biologically active compounds can be incorporated within the interstices of the polymer."); col. 2:15-34; col. 2:40-49; col. 2:53-65; col. 3:55-4:35 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility to as to enable the application of a stable coating onto substrate (i.e. the coating will be able to withstand certain handling, deformation, abrasion,

exposure to various environments, and the like, to which the resulting article will be subjected."); col. 10:45-67; col. 11:34-59; col. 12:15-41.

Bellamkonda '029: Abstract ("A nerve guidance channel for use in regenerating severed nerve is prepared containing a tubular semi-permeable membrane having openings adapted to receive the ends of a severed nerve, and an inner lumen containing the matrix having an adhesive peptide fragment through which the nerve can regenerate."); col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 4:9-14; col. 4:21-39 ("Any suitable hydrogel may be used as the substrate for the bioartificial extracellular matrices of this invention."); col. 4:48-57; col. 5:10-14 ("Several physical properties of the hydrogel matrices of this invention are dependent on gel concentration. Increase in gel concentration may change the gel pore radius, morphology, or its permeability to different molecular weight proteins."); col. 7:13-25; col. 10:28-40 ("Permeable channels with a molecular weight cut-off of 50,000 daltons allowed regeneration of nerves in a mouse sciatic nerve model."); col. 10:41-63; col. 10:64-11:13; col. 12:13-16 ("Preferably the permeable membrane is fabricated to be impermeable to some of these substances so that they are retained in the proximity of the regenerating nerve ends."); col. 12:17-25 ("Briefly, various polymers and polymer blends can be used to manufacture the nerve guidance channel."); col. 12:42-49; col. 19:7-16; col. 23:54-24:55.

Dayton '382: Abstract ("The device comprises a stent which is formed from metal or polymers into a predetermined shape which includes a plurality of holes . . . to provide a desired bending modulus. The stent is then coated with a polymer . . . which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids, with the equilibrium being controlled by charge distribution, concentration and molecular weight of the bioactive substance in relation to the pore size of the polymeric carrier for controlled prolonged release of said bioactive substance."); col. 3:62-4:4:17 ("Among these polymers are polymers having a microporous structure, such as . . . biodegradable polylactic acid polymers, polyglycolic acid polymers . . ."); col. 4:24-33 ("A bioactive substance is preferably admixed in the polymer for elution from the microporous structure of the stent or coating on the stent after implantation. The rate of elution of the bioactive substance is controlled by selecting a pore size for microporous structure . . ."); col. 4: 42-50; col. 4:54-5:3; col. 6:64-7:7 ("The polymer should have a microporous structure with a predetermined pore size."); col. 8:19-33; col. 8:42-59; col. 8:66-9:5; col. 10:1-2.

Burt '036: p. 4:19-33 ("Similarly a wide variety of polymeric carriers may be utilized, representative examples of which include poly(ethylene-vinyl acetate) . . . and copolymers of polylactic acid and polycaprolactone."); p.10:17-25; p.14:9-27 ("As noted above, anti-angiogenic compositions of the present invention comprise an anti-angiogenic factor and a polymeric carrier. In addition to the wide array of anti-angiogenic factors and other compounds discussed above, anti-angiogenic compositions of the present invention may include a wide variety of polymeric carriers, including for example both biodegradable and non-biodegradable compositions."); p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the

composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size."); p.51:1-52:35.

Goldin '568: Col. 1:43-62 ("Release by controlled diffusion may be accomplished by means of containment of the therapeutic agent within a substrate whose small pore size and/or tortuosity of diffusion path thereof limits the diffusion of said agent through the substrate. . . . The therapeutic agent can be incorporated within the diffusion-limiting substrate Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:24-29 ("Microporous membranes for release of proteins by controlled diffusion have been fabricated from ethylene vinyl acetate (EVA), and said membranes have been used in vivo in a manner which demonstrates their therapeutic potential."); col. 5:28-34 (" . . . underlayment material of controlled pore size can be created and used to fabricate a device of optimal porosity . . . and accessibility of the releasable macromolecule to biological material at or beyond the membrane's external surface . . ."); Fig. 1A; col. 11:58-12:14; col. 13:53-65; col. 14:1-28; col. 14:66-15:67; col. 31:57-32:7 ("The device of claim 1 wherein said microporous underlayment comprises a polymer."); col. 32:16-22.

Palmaz '665: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3:47-51 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5: 30-32 ("FIGS. 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon."); Figures 5 and 6.

Palmaz '337: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3:52-56 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5: 19-21; Figures 5 and 6; col. 8: 28-32; col. 9: 24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '762: Col. 10:28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials."); col.3:65-4:2 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 9: 20-25; col. 10: 28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Zaffaroni '254: Abstract ("The wall is formed in at least a part of a microporous material..."); col. 1: 19-23 ("The wall of the device is comprised in at least a part of a microporous material..."); col. 3: 5-10; col. 3: 48-53; col. 4: 47-54 ("Wall 11 is formed of a microporous material the micropores 15 of which contain a drug release rate controlling medium, not shown, permeable to the passage of drug, as by diffusion, or by convection,, or by a concurrent operation of both, but the rate of passage of the drug through the medium in the micropores is lower than the rate of passage of drug through the solid drug carrier."); col. 5: 3-11.

Aebischer: p. 283 (disclosing impermeable polymer layer that restricts passage of treating material).

Dev: p. 273 ("We used a commercially available biomedical grade polyurethane Tecoflex is a biocompatible, flexible, and an elastic membrane-forming polymer.").

Claim 8 [8H] (cont'd): placing the device adjacent to a damaged tissue,

Where Found in the Prior References:

Schwartz '823: Abstract ("The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen."); Figs. 6-9, 13, 15; col. 2:37-40 ("In essence, this improvement makes it possible to provide a stent able to support body lumens and conform to curves or irregularities in body lumens."); col. 2:44-54 ("The composite stent of the present invention can be delivered to the site of the occlusion by catheter and expanded conventionally, causing the film to expand or open radially along with the metallic elements of the stent and to be brought into contact with the body lumen. The polymeric film is flexible and preferably an elastic or stretchable film that is capable of conforming to the movement of the metallic stent elements when expanded into contact with a body lumen."); col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:48-54; col. 3:58-col. 4:6; col. 6:49-52 ("As shown in Fig. 13, the stent can be delivered to the body lumen and expanded (e.g. by use of a balloon catheter) into contact with the body lumen."); col. 6:33-37 ("As shown in Fig. 9, with the angioplasty procedure completed, balloon is deflated and withdrawn leaving stent firmly implanted within vessel with the film held in contact with the vessel."); col. 6:62-68 ("Once in the desired location, the stent can be released from the catheter and expanded into contact with the lumen as shown in Fig. 15 where it can conform to the curvature of the body lumen. The

flexible film is able to form folds which allow the stent elements to readily adapt to the curvature of the body lumen.").

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14 ("The present invention satisfies this need by providing a separate sleeve to encompass the stent and serve as a local drug delivery device to prevent thrombosis."); col. 4:53-55 ("The present invention satisfies this need by providing a separate sleeve to encompass a stent to locally administer drugs to prevent restenosis."); col. 4:58-68 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. . . . Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 5:26-29; col. 6:49-55 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface); col. 8:8-22; col. 8:58-60 ("The films were placed to line the circumference of a 2 cm length of ePTFE grafts, over which a 2 cm long stent was deployed."); col. 9:12-16 ("In addition, polymer-drug films which prevent thrombosis in the baboon and pig AV shunt system can be studied following stent-film placement in carotid, superficial femoral and coronary arteries following balloon injury of those vessels."); col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film

capable of carrying and releasing therapeutic drugs."); col. 1:12-20 ("Stents are typically implanted within a vessel in a contracted state and expanded when in place in the vessel in order to maintain patency of the vessel to allow fluid flow through the vessel. Ideally, the implantation of such stents is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:50-56 ("The stent can be used in coronary arteries or any other part of the vasculature or other body lumen where mechanical opening force is necessary or desirable to keep the vessel open or to maintain the stent flush against the lumen wall, and where an anti-restenosis, anti-proliferative or other types of therapeutic drug or agent is to be simultaneously positioned and diffused."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 2:23-33; col. 5:15-17; col. 7:56-62; col. 9:63-67 ("The deployment of the stent can also be improved by . . . decreasing friction between the vessel or lumen wall and the stent."); col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:52-54 ("The invention provides prostheses which may be inserted into a lumen of a body and fixed to the lumen wall adjacent an area needing treatment."); col. 1:63-66 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery."); col. 2:7-9 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:25-27 ("The current invention contemplates the usage of any prosthesis which elutes drugs locally to treat a lumen in need of repair."); col. 6:36-38; col. 6:56-58 ("The stent shown in Figs. 2 and 4 is a metallic malleable design which may be forced against a lumen wall by a balloon catheter which fixes it into position."); col. 6:64-67 ("The variations of design shown in the embodiments of Figs. 1 and 2 show that the prosthesis of the invention must be secured against a lumen wall and must carry a drug-eluting polymer."); col. 9:67-10:3 ("By including a metal stent within the lumen of the polymeric prosthesis, the polymeric prosthesis is effectively held against the wall of the body lumen by the strength of the metal stent."); col. 10:23-38 ("The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen. This will bring the bioabsorbable element into supporting contact with a body

lumen at an interior position of the body lumen to be treated and will position the bioabsorbable element to deliver drugs to the body lumen. Following the expansion of the stents into luminal contact, the balloon (if the expansion device is a balloon) can be deflated which allows the luminal flow to be restored."); col. 10:46-59; col. 11:10-13; col. 11:17-20; col. 11:50-53 ((b) a body including a plurality of support elements forming an open-ended, radially expandable, self-supporting tubular structuring having an interior surface and an exterior surface."); col. 12:1-15.

Berg '354: Page 2:14-18 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen. Examples of stents which have been successfully applied over a PTCA balloon and radially expanded at the same time as the balloon expansion of an affected artery include the stents disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) which are incorporated herein by reference in their entirety."); p. 2:34-36 ("Metal stents such as those disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) could be suitable for drug delivery in that they are capable of maintaining intimate contact between a substance applied to the outer surface of the stent and the tissues of the vessel to be treated."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:16-18 ("In operation, the stent made according to the present invention can deliver drugs to a body lumen by introducing the stent transluminally into a selected portion of the body lumen and radially expanding the stent into contact with the body lumen.").

Buscemi '450: Col. 3:14-15 ("The stent strengthens an area of the vessel that is in contact with the stent."); col. 3:21-25 ("The tubular main body includes an outer surface and inner surface. The outer surface of the main body faces an inner surface wall of the vessel. The inner surface of the stent faces a stream flowing through the lumen as shown in cross section in Fig. 2."); col. 4:61-64 ("The stent is secured by releasing the stent from compression so that the stent can radially spring out to abut against the inner surface wall of the vessel."); col. 6:49-52; col. 7:27-29; col. 8:9-11.

Ding '536: Col. 5:38-40 ("Surface material should minimize tissue rejection and tissue inflammation and permit encapsulation by tissue adjacent the stent implantation site.").

Dinh '227: Col. 1:32-35 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing mechanical support for the lumen."); col. 8:20-23 ("The term "stent" herein means any device which when placed into contact with a site in the wall of a lumen to be treated, will also place fibrin at the lumen wall and retain it at the lumen wall."); col. 8:37-43; col. 9:18-24 ("The stent is then delivered through the body lumen on the catheter to the treatment site where the stent is released from the catheter to allow it to expand into contact with the lumen wall.").

Domb '055: Abstract ("Preferred embodiments include catheters, tubes, and implants that abut tissue following implantation into the body . . ."); col. 4:25-32; col. 5:27-33; col. 5:49-54;

col. 5:63-6:1 ("Coating that part of the tube, which is in contact with the mucosa, with the drug-loaded polymer provides a sustained release of steroids and antibiotics locally and at high concentration in the area which is critically affected, achieving the same effect as the systemic administration of the drugs without their side effects, throughout the duration of the intubation."); col. 6:8-18; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages.").

Kowligi '782: Abstract; col. 1:18-41; Figs. 2, 3; col. 10:18-67.

Hunter '981: Col. 4:24-38; col. 5:1-6; col. 16:31-56; col. 22:3-7; col. 22:54-58; col. 23:6-13 ("[M]ethods are provided for expanding the lumen of a body passageway, comprising inserting a stent into the passageway, the stent having a generally tubular structure, the surface of the structure being coated with an anti-angiogenic composition . . . such that the passageway is expanded."); col. 23:30-31; col. 23:46-51; col. 24:45-51; col. 24:66-25:5; col. 25:24-29; col. 25:48-54; col. 52:4-8 ("This film is designed to be placed on exposed tissue so that any encapsulated drug is released from the polymer over a long period of time at the tissue site."); 86:56-59; col. 87:11-22; col. 88:19-26.

Lambert '922: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion."); col. 3:54-61; col. 8:1-6.

Lambert '308: Page 3:24-27 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion.").

Myler '563: Col. 3:34-37 ("Stent 10 is illustrated in its expanded position at a treatment location adjacent vascular wall in an artery, in accordance with one aspect of the present invention."); col. 4:53-56 ("The exterior surface of the envelope which will contact the arterial wall is optionally made porous to enable the release of drugs from the envelope and/or stent to the treatment site."); col. 10:12-14 ("The balloon is inflated, thereby expanding the stent radially outwardly until it contacts either a previously dilated, or presently stenosed wall."); col. 10:56-61; col. 11:63-65 ("Once the stent has been positioned at the treatment site, axial elongating tension is released, and it is permitted to radially expand against the lumen wall."); col. 13:15-17 ("The exterior coating which will contact the arterial wall is optionally made porous to enable the release of drugs to the treatment site.").

Palmaz '417: col. 4:25-37 (" . . . expanding a portion of the catheter associated with the prostheses to force at least one of the prostheses radially outward into contact with the body passageway . . .").

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); Figs. 1 and 2; col. 9:18-10:3.

Strecker '746: Figs. 7 & 8.

Schiraldi '243: Col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Valentini '029: Abstract ("In particular, tubular channels which have a smooth inner surface and longitudinally oriented trabeculae result in significantly larger regenerated nerve cables and higher numbers of regenerated myelinated axons."); Figure 3; col. 2:32-35 ("Medical devices employing such selectively permeable materials, particularly semipermeable tubular devices having smooth inner skins, are disclosed for use in regenerating nerves."); col. 2:58-3:14; col. 5:33-41; col. 6:14-24.

Bawa '279: Col. 6:40-44; col. 12:29-34.

Wood '066: Col. 2:67-3:32 ("The object of this invention is to provide means for delivery effective dosages of therapeutic agents to sites of trauma such as wounds, thermal or chemical burns, ulcers, lesions, or surgical sites.").

Aebischer '486: Fig. 1.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:63-2:2; col. 2:21-32; col. 2:33-38; col. 2:39-46; col. 3:63-4:31 ("It can be of advantage for the lining to be of several layers, each impregnated with different medications. . . . It has also been demonstrated practical for the inner layer of the lining to be impregnated with antithrombotics

and the outer with antiproliferatives and/or other medicational substances.); Fig. 4; col. 5:18-20 ("Fig. 4 is a view similar to that of Fig. 2 of an endoprosthesis with a multiple-layer lining and with its ends coated with medication,"); col. 5:34-41 ("The endoprosthesis . . . is completely enclosed in an inner lining component and an outer lining component."); Fig. 7; col. 6:30-44 ("The endoprosthesis 40 in the embodiment illustrated in Fig. 7 comprises a lining 42 and 43 in the form of a double walled sleeve. The outer lining component 43 of the in-place and expanded stent rests against the inner surface 46 of the blood vessel. Inner lining component 42 rests against the stent."); col. 7:16-35; col. 7:48-65; col. 8:19-10:19.

Lambert '246: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion.").

Bellamkonda '029: Fig. 6.

Dayton '382: Abstract ("The stent is then coated with a polymer or is formed from a polymer which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids . . ."); col. 4:4-10; col. 6:64-7:7; col. 8:18-19 ("a polymer forming the exterior surface of said stent for operative contact with said tissue . . .").

Burt '036: p.14:9-27; p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size.").

Goldin '568: Figs. 5A-5F; col. 9:7-12 (" . . . a substance that, when implanted in or juxtaposed against a living body . . ."); col. 22:46-23:3.

Palmaz '665: Col.3: 55-65 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into the body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded..."); col. 5:9-13; Figure 4; col. 8:9-14.

Palmaz '762: Col. 4: 14-19 (...expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway..."); col. 4: 53-56; col. 5: 43-45; col. 9: 1-6.

Palmaz '337: Col. 3:60-4:2 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into a body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded, whereby the intraluminal graft prevents the body passageway from collapsing and decreasing the size of the expanded lumen."); col. 4: 36-40; col. 5: 32-34; col. 7: 28-36; col. 8: 17-22.

Zaffaroni '254: Col. 7: 18-25 ("Secondly, the carrier contacts and bathes the inner surface of wall 11 for facilitating drug transfer from the carrier to the wall so that drug molecules can dissolve in a diffusive medium in the microporous wall and migrate through it to the outer surface thereof.").

Aebischer: Fig. 2A (disclosing one major surface facing the nerve stumps).

Dev: Abstract ("Polymer-coated stents could be used for local drug delivery to the vessel wall."); p. 273 (" . . . to compare these two drugs with respect to kinetics of their delivery to the arterial wall with the stent in place . . .").

Claim 8 [8I] (cont'd): whereby the placed device results in directional presentation of the at least one treating material.

Where Found in the Prior References:

Peterson '166: Abstract ("A time-release chemical delivery system in which a bioactive compound is attached to a polymeric biodegradable carrier by a hydrolysable bond is disclosed. The bioactive compound can either be bound directly to the polymer or be attached to the polymer via a spacer group."); col. 1:28-38; col. 1:51-55 ("Another object of the instant invention is to provide a bioactive compound via covalent bonding to a polymeric backbone so that upon hydrolysis of said covalent bond said bioactive compound is released in active, unmodified form."); col. 1:60-62; col. 1:67-col. 2:2; col. 2:40-50 ("A further requirement of the polymeric carriers are that they contain a pendant group to which a reactive compound may be directly attached by a hydrolyzable bond or to which a spacer unit may be attached with the reactive compound attached to the spacer unit by a hydrolysable bond. Typically, the space [sic] unit will also be attached to the polymeric carrier by a hydrolyzable bond."); col. 2:51-60; col. 3:67-4:2; col. 4:3-7 ("The use of a spacer group may also provide desirable changes in drug release rate by allowing ease of hydrolysis of the drug."); col. 4:8-19; col. 4:56-5:2; col. 6:28-55; col. 6:55-62 ("Since the proximity of the reactive carboxyl group to the polymer backbone may interfere with the addition of a bioactive compound, especially a large molecule, and with the subsequent hydrolysis of a covalent bond formed by such condensation reaction, the use of a spacer group, preferably linear in nature, may be preferred in this invention."); col. 6:65-col.7:28 ("To be effective as hydrolysable carriers the polymers of this invention must have pendant reactive sites to which a bioactive compound may be attached. . . . These functional groups may react with functional groups of the bioactive compound to form a hydrolysable bond. The hydrolysable bond may be direct between the pendant group of the polymer and the reactive compound or it may be first reacted with a spacer unit which contains a similar reactive functional group. . . . The reactivity of the reactive sites is also affected by the distance of the reactive site from the backbone of the polymer."); col. 7:32-53 ("Spacer groups may be utilized in the practice of the instant invention to provide a hydrolysable unit which spaces the reactive compound further from the carrier backbone. As indicated hereinabove, the polymeric units may

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contain long pendant chains which place the reactive site on the pendant group further away from the carrier backbone. . . ."); col. 7:57-62 ("Bioactive compounds useful in this invention are those which contain a group which may react to form a bond with a pendant group or a spacer group. The bond is preferably hydrolysable and in particular are esters, including sulfates or phosphate esters, amides, carbonates and urethane bonds."); col.8:25-28 ("The reactive compound which is released over a period of time in the instant invention may be one which has a pharmacological affect upon the host, for example, a contraceptive drug in an animal."); col. 8:34-49 ("Factors which affect the release rate and the rate of absorption into the body of the host include . . . the composition of the polymer backbone, the length and character of the spacer groups and the character of the pendant groups The spacing of the bulky drug or chemically reacted compound from the polymer also affects the rate of release."); col. 11:25-12:4 (" . . . a bioactive compound chemically attached to said carrier by a hydrolysable bond, said bioactive compound containing a group which reacts with a group on the biodegradable polymer to form a hydrolysable bond and being effective in small dosages to produce a biological effect within said host upon release into the host by hydrolysis of the hydrolyzable bond."); col. 12:14-24 ("The chemical delivery system of claim 1 wherein said bioactive compound is indirectly coupled to said carrier by a hydrolyzable bond to a spacer compound. . . . The chemical delivery system of claim 7 wherein said spacer compound is coupled to said bioactive compound by a hydrolyzable bond."); col. 12:28-30.

Schwartz '823: Col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:64-4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof."); col. 7:1-4 ("In yet another aspect of the present invention, various therapeutic substances can be incorporated in or applied to the polymeric film to provide such substances to the blood or to the lumen wall."); col. 7:14-25 ("Application of the therapeutic substance to the film can include applying it on the surface of the film or incorporating it into the film as it is made. For example, microcapsules can be used to carry the therapeutic substance either in or on the film and to provide timed-release of the substance to the blood, or to the blood vessel or both."); col. 7:25-34 ("Microcapsules containing one type of therapeutic substance could be provided on one side of the film and microcapsules containing another therapeutic substance could be incorporated on the other side of the film, thus providing a stent according to the present invention which provides one type of therapeutic substance (e.g. an anti-thrombotic drug) to the blood and another type of therapeutic substance (e.g. an antiproliferative drug) to the vessel wall."); col.8:5-11 ("The resulting stent has microcapsules containing one therapeutic substance on the inside (and able to contact blood once implanted in a blood vessel) and microcapsules containing a second therapeutic substance on the outside (and able to contact the vessel wall when implanted in contact with the vessel wall)."); col. 8:46-47.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14; col. 4:53-55; col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-33; col. 5:34-6:23 ("Many polymers can also be used to make the sheath, including biodegradable and non-degradable polymers. The polymer is selected depending on the drug selected, the polymer's compatibility with a subject and the ultimate pharmacologic effect desired. . . . Another alternative would be to use a polymer which is biodegradable over a short period of time. Naturally, the opposite characteristics would be selected for a desired prolonged release. The characteristics of the particular polymer for these purposes is well known to the skilled artisans or can be determined by reference to standard references . . ."); col. 6:39-41 ("The initial prototype is a sleeve of polymer, either degradable or non-degradable, that covers the entire stent (Fig. 3)"); col. 6:64-68 ("The duration of drug delivery is accurately predicted by the characteristics of the polymer. For example, if the polymer is biodegradable, then the rate and duration of drug delivery is related to the thickness of the polymer."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface."); col. 8:23-54; col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33 ("In combination, a hollow tubular stent having a predetermined length and a separate sheath removably encompassing at least a portion of said hollow tubular stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug."); col. 11:11-12 ("14. The sheath of claim 1, wherein the polymer is biodegradable."); col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally

referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 5:4-9 ("The primary function of the sheet of polymeric material is to deliver therapeutic agents or drugs to help prevent thrombosis and/or restenosis."); col. 5:49-6:25 ("The polymeric material is preferably bioabsorbable, and is preferably loaded or coated with a therapeutic agent or drug . . ."); col. 7:23-25; col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:63-2:6 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery. The prostheses may be completely biodegradable or may be bioabsorbable in whole or incorporated into the lumen wall as a result of tissue overgrowth, i.e. endothelialization. Alternatively, the prostheses may be biostable in which case the drug is diffused out from the biostable materials in which it is incorporated."); col. 2:28-30 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 2:55-58; Fig. 5; col. 6:5-10 ("When drugs are delivered locally via the prosthesis of the invention, they may be at therapeutic levels at the diseased site while at the lower limits of detectability in the bloodstream. So little drug is required for effective local treatment of a lumen that the drug may not be detectable in blood samples."); col. 6:36-38; col. 6:59-63 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously. the polymer may be biostable or bioabsorbable. If biostable, the drug would diffuse out of the polymer."); col. 6:64-67; col. 7:19-23; col. 7:53-55 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 7:59-8:25; col. 8:26-31 ("The compound which is preferred is a polyphosphate ester. Polyphosphate ester is a compound such as that disclosed in U.S. Pat. Nos. 5,176,907; 5,194,581; and 5,656,765 issued to Leong which are incorporated herein by reference. Similar to polyanhydrides, polyphosphate ester is being researched for the sole purpose of drug delivery."); col. 8:40-9:22 ("It is the hydrolytic instability of the phosphorous ester bond which makes this polymer attractive for controlled drug release

applications. A wide range of controllable degradation rates can be obtained by adjusting the hydrophobicities of the backbones of the polymers and yet assure biodegradability. The functional side groups allow for the chemical linkage of drug molecules to the polymer."); col. 12:12-15.

Berg '354: Page 2:27-31 ("Other methods of providing therapeutic substances to the vascular wall include simple heparin-coated metallic stents, whereby a heparin coating is ionically or covalently bonded to the stent. Still other methods of providing therapeutic substances to the vascular wall by means of stents have also been proposed such as in US-A-5102417 (Palmaz), WO-91/12779 "Intraluminal Drug Eluting Prosthesis" and WO-90/133332 "Stent With Sustained Drug Delivery".); p. 3:7-9; p. 3:22-23 ("It also provides a drug-containing stent which allows for a sustained release of the drug to vascular tissue."); p. 4:25-27 ("The ratio of therapeutic substance to polymer in the solution will depend on the efficacy of the polymer in securing the therapeutic substance onto the stent and the rate at which the coating is to release the therapeutic substance to the tissue of the blood vessel."); p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Abstract ("A stent made of biodegradable material includes a drug that is released at a rate controlled by the rate of degradation of the biodegradable material."); col. 1:61-63; col. 2:6-8 ("The mechanism of biodegradation is described as hydrolysis resulting in degradable products excreted in urine or reabsorbed into tissues."); col. 2:49-52 ("Also desired are stents which can deliver drugs or biologically active agents at a controlled rate to blood passing through the vessel lumen as well as to the vessel wall."); col. 2:56-61 ("The biodegradable stent is made from at least one biodegradable material that is also biocompatible and includes a drug which is released into the lumen of the vessel at a rate controlled by the rate of degradation of the biodegradable material."); col. 3:11-12 ("The rate of drug release is controlled by the rate of degradation of the biodegradable materials."); col. 3:53-55; col. 4:12-14; col. 4:23-25 ("The present invention further includes a main body having more than one biodegradable interior film layer."); col. 4:65-5:5 "In the most preferred embodiment, the biodegradable stent of the present invention is made of biodegradable materials that are also biocompatible. By biodegradable is meant that a material will undergo breakdown or decomposition into harmless compounds as part of a normal biological process"); col. 5:11-19 ("Suitable biodegradable materials for the main body of the stent of the present invention include polylactic acid, polyglycolic acid (PGA), collagen or other connective proteins or natural materials, polycaprolactone, hyaluric acid, adhesive proteins, co-polymers of these materials as well as composites and combinations thereof and combinations of other biodegradable polymers."); col. 5:21-37; col. 5:38-45 ("Consequently, the presence of different biodegradable materials in the stent permits the stent to degrade in a predictable, orchestrated fashion."); col. 5:46-54 ("As the stent biodegrades, drugs are administered to the surrounding tissue or to the blood stream. Thus, the rate of drug release is controlled by the rate of degradation of the biodegradable materials."); col. 6:3-8; col. 6:45-59; col. 7:2-9; col. 7:32-8:9; col. 8:27-30.

Ding '536: Abstract ("In one embodiment, the surface is provided with sites of high electronegativity species by coating with fluorosilicone which aid in controlled elution,

particularly the initial release rate, and reduce thrombogenic activity."); col. 2:38-42 ("Such an approach is described by Winters, et al., in U.S. Pat. Nos. 5,182,317; 5,262,451 and 5,338,770 in which the amine functional groups of the active material are covalently bonded using a polyethylene oxide (PEO) on a siloxane surface."); col. 2:43-46 ("Another approach is described in U.S. Pat. No. 4,613,665 to Larm in which heparin is chemically covalently bound to impart a non-thrombogenic surface to the material."); col. 3:19-27 ("Accordingly, it is a primary object of the present invention to provide a coating and process for coating a stent to be used as a deployed stent prosthesis, the coating being capable of effective controlled long-term delivery of biologically active materials. Another object of the invention is to provide a coating and process for coating a stent prostheses using a biostable hydrophobic elastomer in which biologically active species are incorporated within a coating."); col. 6:16-27 ("The mechanism of incorporation of the biologically active species into the surface coating and egress mechanism depend both on the nature of the surface coating polymer and the material to be incorporated. The mechanism of release also depends on the mode of incorporation. The material may elute via interparticle paths or be administered via transport or diffusion through the encapsulating material itself."); col. 6:28-34; col. 6:35-48; col. 10:35-40 ("In addition, because of the negative charges on the heparin itself, the electro-negativity of the fluorosilicone topcoat may be, at least in part, responsible for the modified heparin release kinetic profile."); col. 12:62-67 ("Whereas the polymer of the coating may be any biostable elastomeric material capable of being adhered to the stent material as a thin layer, hydrophobic materials are preferred because it has been found that the release of the biologically active species can generally be more predictably controlled with such materials. Preferred materials include silicone rubber elastomers and biostable polyurethanes specifically.").

Dinh '227: Col. 2:26-32; col. 3:10-14; col. 5:53-55 ("Suitable polymers could also be biodegradable polymers such as polyphosphate ester, polyhydroxybutyrate valerate, polyhydroxybutyrate-co-hydroxyvalerate and the like."); col. 6:13-22; col. 6:32-50; col. 6:50-56; col. 7:10-13 ("The adhesion of the coating and the rate at which the drug is delivered can be controlled by the selection of an appropriate bioabsorbable or biostable polymer and by the ratio of drug to polymer in the solution."); col. 7:13-23; col. 7:30-44; col. 7:45-51 ("The polymer used can be bioabsorbable or biostable polymer. Suitable bioabsorbable polymers include poly(L-lactic acid), poly(lactide-co-glycolide) and poly(hydroxybutyrate-co-valerate). Suitable biostable polymers include silicones, polyurethanes, polyesters, vinyl homopolymers and copolymers, acrylate homopolymers and copolymers, polyethers and celluloses."); col. 9:17-18; col. 12:38-50.

[Domb '055: Abstract ("Preferred polymeric coatings are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); col. 3:54-62 ("In the preferred embodiments, these have utilized bioerodible polymers as the matrix for the drug to be released, usually as a function of diffusion and erosion of the polymer. The advantage of these drug delivery systems is that they provide a sustained/continuous release of drugs locally and at a relatively high concentration in areas of the body, without systemic side-effects, throughout the duration of their release."); col. 4:11-13 ("It is a further object of the present invention to provide medical devices having prolonged low-dose, localized release of anti-microbial and anti-inflammatory agents."); col. 4:33-36; col. 5:27-33; col. 5:41-45 ("The drug-loaded polymer provides a sustained release

of steroids and antibiotics locally and at a relatively high concentration in that area which is critically affected, without the side-effects of the systemic administration of the same drugs, throughout the duration of intubation."); col. 5:49-54; col. 5:60-6:1 ("An esophageal silicone stent coated with a film of polymer can be used to provide a site-specific controlled release of corticosteroids and antibiotics."); col. 6:3-7; col. 6:24-26 ("Examples of suitable polymers include ethylene vinyl acetate, polyurethane, silicones, hydrogels, polyurethane, and polyvinyl chloride."); col. 6:42-45 ("Release is a function of diffusion of the agent from the polymeric matrix, and varies by size, concentration and solubility of the agent, as well as by thickness and chemical composition of the polymeric matrix."); col. 7:10-20; col. 7:25-29; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 11:36-38 ("The medical device of claim 1, wherein the polymer is selected from the group consisting of polyurethane, ethylene vinyl acetate, silicones, hydrogels, and polyvinyl chloride."); col. 11:39-44; col. 12:1-7; col. 12:11-22; col. 12:23-25; col. 12:26-31; col. 12:32-42.

Fox '096: Abstract ("A method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers, and antimicrobial agents . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 3:55-67 ("The polymeric coating agent component of the coating vehicle of the present invention is selected from the group consisting of biomedical polyurethanes, biomedical silicones, biodegradable polymers and combinations thereof."); col. 4:30-5:35; col. 7:22-25; col. 7:28-32; col. 11:34-48 ("Suitable biodegradable polymers include the homopolymers poly(glycolic acid), poly(D-lactic acid), poly(D,L-lactic acid), poly(D,L-ethyl-glycolic acid), poly(dimethylglycolic acid), poly(D,L-methylethylglycolic acid), and poly(E-caprolactone), as well as biodegradable polyhydroxy butyric acid and mixtures thereof. A preferred biodegradable polymer is polylactic acid (PLA)."); col. 11:51-56 ("The biodegradable polymer modulates the rate of release of antimicrobial drugs."); Table IV; col. 12:24-41 ("Suitable biomedical poly(lactic) polymers include the poly(L-lactide), poly(D-lactide) and the poly (D-L-lactic acid). . . . The poly(lactic acid) polymers are bioerodible, and while they can be used alone, it is preferred that they be combined with either a biomedical polyurethane or a biomedical silicone."); col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages."); col.

18:19-25; col. 20:54-58; col. 28:13-18; col. 29:38-40 (Adding a biodegradable material containing anti-microbial agents to the adhesive to provide controlled-release through degradation."); col. 36:21-31; col. 36:47-51; col. 36:65-37:7; col. 37:29-31; col. 37:56-57; col. 37:63-65; col. 37:66-38:9; col. 38:24-30; col. 39:39-41; col. 40:33-34; col. 40:39-42.

Hunter '981: Abstract; col. 3:42-61 ("A wide variety of molecules may be utilized within the scope of the present invention as anti-angiogenic factors, including for example Anti-Invasive Factor, retinoic acids and their derivatives, paclitaxel including analogues and derivatives thereof, Suramin, Tissue Inhibitor of Metalloproteinase-1, Tissue Inhibitor-1 and Plasminogen Activator Inhibitor-2, and lighter "d group" transition metals. Similarly, a wide variety of polymeric carriers may be utilized, representative examples of which include poly (ethylene-vinyl acetate) (40% cross-linked), poly (D,L-lactic acid) oligomers and polymers, poly (L-lactic acid) oligomers and polymers, poly(glycolic acid), copolymers of lactic acid and glycolic acid, poly(caprolactone), poly(valerolactone), poly(anhydrides), copolymers of poly(caprolactone) or poly(lactic acid) with polyethylene glycol, and blends thereof."); col. 5:27-32; col. 12:23-35 ("As noted above, the present invention provides compositions comprising an anti-angiogenic factor, and a polymeric carrier."); col. 16:31-56 ("Anti-angiogenic compositions of the present invention are provided in a wide variety of polymeric carriers, including for example both biodegradable and non-biodegradable compositions. Representative examples of biodegradable compositions include albumin, gelatin, starch, cellulose, dextrans, polysaccharides, fibrinogen, poly (D,L lactide), poly (D,L-lactide-co-glycolide), poly (glycolide), poly (hydroxybutyrate), poly (alkylcarbonate) and poly (orthoesters) Representative examples of nondegradable polymers include EVA copolymers, siliconerubber and poly (methylmethacrylate). Particularly preferred polymeric carriers include poly (ethylene-vinyl acetate)(40% cross-linked), poly(D,L-lactic acid) oligomers and polymers, poly (L-lactic acid) oligomers and polymers, poly (glycolic acid), copolymers of lactic acid and glycolic acid, poly (caprolactone), poly (valerolactone), polyanhydrides, copolymers of poly (caprolactone) or poly (lactic acid) with polyethylene glycol and blends thereof."); col. 16:31-56; col. 16:66-17:6 ("Anti-angiogenic factors may be linked by occlusion in the matrices of the polymer, bound by covalent linkages, or encapsulated in microcapsules. Within certain preferred embodiments of the invention, anti-angiogenic compositions are provided in non-capsular formulations such as microspheres . . . pastes, threads of various size, films and sprays."); col. 17:7-26; col. 17:41-43 ("Anti-angiogenic compositions may also be prepared, given the disclosure provided herein, for a variety of other applications."); col. 18:15-49 ("Within further aspects of the present invention, polymeric carriers are provided which are adapted to contain and release a hydrophobic compound, the carrier containing the hydrophobic compound in combination with a carbohydrate, protein or polypeptide. Within certain embodiments, the polymeric carrier contains or comprises regions, pockets, or granules of one or more hydrophobic compounds."); col. 47:58-49:7; col. 56:45-57; col. 57:17-31; col. 59:65-60:48; col. 59: 32-59 ("Poly(e-caprolactone) is an aliphatic polyester which can be degraded by hydrolysis under physiological conditions and it is non-toxic and tissue compatible."); col. 69:19-62; col. 77:43-55 ("The release of paclitaxel, in this case, is dominated by polymer degradation."); col. 78:58-79:5 ("Although not specifically set forth above, a wide variety of other polymeric carriers may be manufactured, including for example . . ."); col. 84:62-86:24; col. 86:60-67.

Kinsella '608: Col. 11:18-24 ("Drug delivery systems that can be valuable include drug-impregnated polymer-coated metallic stents [and] biodegradable drug-eluting polymer stents . . .").

Kowligi '782: Col. 4:16-27 ("In regard to elastomeric coating 38 shown in Fig. 2, such elastomeric coating is selected to be a biocompatible elastomers and may be selected from the group consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 10:18-27; col. 10:28-32 ("The implantable vascular graft recited by claim 1 wherein said elastomers is selected from the group of elastomers consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 10:43-50; col. 10:60-67.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 1:46-55 ("Release of heparin from intravascular catheters in quantities sufficient to decrease thrombosis on the catheter has been achieved by either covalently bonding a charged molecule to a polymer or incorporating a large nonmobile charged molecule on the surface of the polymer . . ."); col. 1:62-65; col. 2:16-35; col. 2:40-50 ("In accordance with the present invention, there is provided a method for preparing a system suitable for localized delivery of biologically active compounds to a subject."); col. 2:55-67; col. 3:8-12; col. 3:29-49; col. 4:10-17; col. 7:29-32; col. 7:38-41; col. 8:62-9:19 ("Adventitia overlying the stent contained 360 times the concentration of forskolin in the blood and 305 times the concentration of forskolin in the contralateral artery. . . . In a similar model, etretinate, a retinoic acid analog, develops concentrations in the media of 250 ng/mg tissue at 24 hours. At 24 hours, this concentration was over 2000 times the concentration in the blood."); col. 9:31-37 ("These data demonstrate that a polyurethane coated nitinol stent is capable of delivering a lipophilic drug in high local concentration in the vessel wall. The large 450 fold differential of local tissue levels of forskolin over blood levels reflects the capability of this delivery system to provide high local concentration and potentially higher efficacy, with lower risk of systemic side effects."); col. 12:21-22 ("The method in accordance with claim 1, wherein the biologically active compound is a lipophilic compound."); col. 12:27-30 ("The method in accordance with claim 1, wherein the biologically active compound is a hydrophilic compound, said method further comprising linking the hydrophilic compound to a lipophilic carrier.").

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p. 2:10-19 ("Release of heparin from intravascular catheters in quantities sufficient to decrease thrombosis on the catheter has been achieved by either covalently bonding a charged molecule to a polymer or incorporating a large nonmobile charged molecule on the surface of the polymer . . ."); p. 2:25-30; p. 3:10-31 ("Upon long-term exposure of a prosthetic article to physiological

conditions, the biologically active compound is slowly released from the treated polymer."); p. 4:2-12; p. 4:17-31; p. 15:25-16:14 ("Adventitia overlying the stent contained 360 times the concentration of forskolin in the blood and 305 times the concentration of forskolin in the contralateral artery. . . . In a similar model, etretinate, a retinoic acid analog, develops concentrations in the media of 250 ng/mg tissue at 24 hours. At 24 hours, this concentration was over 2000 times the concentration in the blood."); p.16:27-34 ("These data demonstrate that a polyurethane coated nitinol stent is capable of delivering a lipophilic drug in high local concentration in the vessel wall. The large 450 fold differential of local tissue levels of forskolin over blood levels reflects the capability of this delivery system to provide high local concentration and potentially higher efficacy, with lower risk of systemic side effects."); claim 14 ("The method in accordance with claim 1, wherein the biologically active compound is a lipophilic compound."); claim 16 ("The method in accordance with claim 1, wherein the biologically active compound is a hydrophilic compound, said method further comprising linking the hydrophilic compound to a lipophilic carrier."); claim 26.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8; p. 1:56-58.

Mitchell '711: Col. 6:24-28 ("Suitable solid carrier include, for example, calcium phosphate, magnesium stearate, talc, sugars, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, sodium carboxymethyl cellulose, polyvinylpyrrolidone, low melting waxes and ion exchange resins.").

Morris '781: Col. 10:50-54 ("Suitable solid carriers include, for example, calcium phosphate, magnesium stearate, talc, sugars, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, sodium carboxymethyl cellulose, polyvinylpyrrolidone, low melting waxes and ion exchange resins.").

Morris '182: Page 6:54-56 ("Suitable solid carriers include, for example, calcium phosphate, magnesium stearate, talc, sugars, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, sodium carboxymethyl cellulose, polyvinylpyrrolidone, low melting waxes and ion exchange resins.").

Myler '563: Col. 4:57-59; col. 4:60-67 ("[T]he stent can be provided with a solid drug carrier such as an impregnated porous solid wall or sponge for timed drug delivery."); col. 5:39-41 ("For the above reasons, even the expanded pores for drug delivery should be small enough to maximize or prevent cell penetration, but large enough for drug delivery."); col. 13:15-18 ("The exterior coating which will contact the arterial wall is optionally made porous to enable the release of drugs to the treatment site.").

Palmaz '417: Col. 11:8-11; col. 11:26-34 ("Examples of biologically compatible coatings would include coatings made of absorbable polymers such as those used to manufacture absorbable sutures. Such absorbable polymers include polyglycoides, polyacoides, and copolymers thereof. Such absorbable polymers could also contain various types of drugs, whereby as the coating is absorbed, or dissolves, the drug would be slowly released into the body passageway.").

Tice '330: Col. 3:20-33 ("A preferred group of polymeric wall forming materials includes those which are biodegradable such as aliphatic polyesters including polylactide, polyglycolide, polycaprolactone and copolymers thereof."); col. 8:38-51.

Thies '317: Abstract ("The capsules provide controlled release of the active agent over a prolonged period of time."); col.1:15-19 ("The art of encapsulation has developed various processes and methods for individually coating particular matter for purposes of controlled release or metering out of an active agent over a prolonged period."); col. 2:26-38; col. 2:43-47; col. 2: 48-51; col. 3:41-4:2; col. 6:35-39 ("Therefore, the presence of a soluble alkali metal silicate in the interior of the capsule causes much of the capsule coating material to simply disappear upon immersion in water thereby causing accelerated release of the active agent."); col. 7:36-11:68; col. 12:10-40; col. 13:4-14:3.

Tice '840: Col. 2:32-34; col. 2:38-55 ("The polymeric matrix material of the microparticles of the present invention must be a biocompatible and biodegradable polymeric material. . . . Suitable examples of polymeric matrix materials include poly (glycolic acid), poly-d,l-lactic acid, copolymers thereof, copolyoxalates, polycaprolactone, poly (lactic acid-caprolactone), and the like."); col. 2:56-3:8 ("The molecular weight of a polymer is also important from the point of view that molecular weight influences the biodegradation rate of the polymer. The drug can also be released from the microparticles as the polymeric excipient bioerodes. By an appropriate selection of polymeric materials a microparticle formulation can be made such that the resulting microparticles exhibit both diffusional release and biodegradation release properties."); col. 10:56-11:15; col. 12:6-9.

Tice '025: Col. 2:32-34; col. 2:38-55 ("The polymeric matrix material of the microparticles of the present invention must be a biocompatible and biodegradable polymeric material. . . . Suitable examples of polymeric matrix materials include poly (glycolic acid), poly-d,l-lactic acid, copolymers thereof, copolyoxalates, polycaprolactone, poly (lactic acid-caprolactone), and the like."); col. 2:56-3:8 ("The molecular weight of a polymer is also important from the point of view that molecular weight influences the biodegradation rate of the polymer. The drug can also be released from the microparticles as the polymeric excipient bioerodes. By an appropriate selection of polymeric materials a microparticle formulation can be made such that the resulting microparticles exhibit both diffusional release and biodegradation release properties."); col. 10:51-11:5; col. 12:1-4.

Lapka '244: Abstract; col. 2:35-63; col. 4:35-57 ("Among the bioabsorbable polymer materials suitable for use in the invention may be mentioned poly(lactic acid) or polylactic acid polymers, such as dl-poly(lactic acid) (or poly(dl-lactic acid)) polymers, poly-(glycolic acid) polymers, poly(hydroxybutyric acid) polymers and lactide/glycolid copolymers."); col. 4:58-5:5 ("The solid injectable drug material which constitutes the core material of the microcapsules may be any such injectable drug material for which it is desired to establish a long-acting, sustained release delivery system."); col. 32:5-16; col. 32:20-21; col. 32:28-34; col. 32:35-39 ("The process according to claim 8 wherein the core material is selected from the group consisting of cyclazocine, tetracycline, ehtisterone, digitoxin, antimony potassium tartrate, salmon calcitonin, ACTH, lypressin, sommatostatin, and insulin.").

Kent '189: Abstract; col. 1:12-28 ("The invention relates to a microcapsule composition comprising a core containing at least one water-soluble, hormonally active polypeptide and optionally a polymer hydrolysis modifying agent encapsulated in a biodegradable, biocompatible copolymer excipient. These compositions have sustained release characteristics. More specifically it relates to microcapsules wherein the core contains water-soluble polypeptides which are lutenizing hormone-releasing hormones, or mammalian growth hormones or polypeptides having thymosin-like activity and optionally an organic acid or its salts, or an acidic, neutral or basic inorganic salt which is capable of modifying the hydrolysis rate of the polymer excipient, encapsulated by a biocompatible, biodegradable excipient."); col. 1:50-58; col. 2:4-7 ("The encapsulating material may be a synthetic polymer comprising either poly(o-hydroxycarboxylic acids), poly(lactones), poly(acetals), poly(orthoesters) or poly(orthocarbonates)."); col. 11:5-38; col. 11:39-13:35 ("The number and type of encapsulating excipients which may be effectively used to practice this invention is limited only by the requirements that the material be biocompatible and biodegradable. . . . Various combinations of alpha hydroxycarboxylic acids and certain lactones can be condensed to form such polymers, particularly lactic acid and glycolic acid or combinations thereof. . . . Similar biocompatible polymers based on glycolic acid and glycerol and the like are also known. . . . Several new biocompatible, biodegradable polymers derived from polyorthoesters and polyorthocarbonates also may be effectively used as encapsulating excipients in the practice of this invention. . . . There are also known polyacetals and polyorthoesters useful for this purpose . . ."); col. 17:42-18:67.

Tice '268: Abstract ("A compatible, biodegradable microcapsule delivery system for active ingredients, including hormonally active peptides, proteins, or other bioactive molecules . . ."); col. 1:32-46 ("More recently a polymer of poly(D,L-lactide-coglycolide) (DL-PLG), which is biodegradable and biocompatible with living tissue, has been used in microcapsules for longer acting delivery systems. Systems of microencapsulated active ingredients in polymers and copolymers have been used to achieve controlled release of chemical and biological pharmaceuticals."); col. 1:47-2:14 ("The microcapsule systems described in the above-publications all share a common feature in that the release of the compound is controlled by the porosity and/or erosion of a polymer continuum."); col. 2:45-53; col. 3:40-47 ("It should be noted, however, that other polymers besides poly(D,L-lactide-co-glycolide) may be used. Examples of such polymers include, but are not limited to: polyacetal polymers, polyorthoesters, polyesteramides, polycaprolactone and copolymers thereof, polycarbonates, polyhydroxybuterate and copolymers thereof, polymaleamides, copolyaxalates and polysaccharides."); col. 11:15-41.

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); col. 3:13-18; col. 3:34-38 ("In a preferred technique, one or more finishing coats of a second solution containing the same or another biocompatible polymer without the carrier is applied to provide an impermeable or substantially less permeable outer surface."); col. 4:29-34 ("In this embodiment, active factor 26 is incorporated within the membrane wall 12. The outer membrane surface 28 is nonporous, while porous inner membrane surface 22 allows for the diffusion therethrough of active factor 26."); col. 4:66-5:11 ("The membrane of the channel may be fabricated from any biocompatible polymers, such as, for example, polyethylene

vinyl-acetate (EVA). . . . Preferable acrylates include methacrylates or hydroethylmethacrylates. The membrane instead may be composed of a bioresorbable biocompatible polymer, such as a polyanhydride, polyester, or mixtures thereof."); col. 5:18-28 ("In a preferred embodiment of the invention, the outer surface of the membrane is impermeable to solutes of any size, while the inner membrane surface contains pores [that] enable the active factors to diffuse out of the membrane and into the lumen of the channel."); col. 5:44-6:10; col. 6:17-22 ("The layering procedure allows deposition of an impermeable coat on the outer surface of the device, insuring that the active factors incorporated into the membrane walls will be inhibited from diffusing through the external surface, and will diffuse only through the inner membrane surface into the lumen of the channel."); col. 9:18-10:3; col. 10:10-12.

Folkman '560: Col. 1:56-2:23; col. 2:43-68; col. 3:18-23 ("The polymer matrixes, which are suitably used in the present invention, are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:36-51 ("Typical polymeric material suitable for forming the matrix . . . include . . . alkylene-vinyl acetate copolymers . . . crosslinked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:52-4:26 ("In the presently preferred embodiment the polymeric materials useful for forming the matrix are the ethylene vinyl ester copolymers of the general formula . . ."); col. 8:17-18; col. 11:56-12:20; col. 12:28-31; col. 12:36-43; col. 12:52-54 ("The therapeutic system for the administration of insulin according to claim 1, wherein the polymeric matrix is ethylene-vinyl acetate copolymer."); col. 12:59-61.

Cohen '496: Abstract; col. 2:46-66 ("In general, the invention features an improved method of making such a body, in which a biologically active material and the polymer below the glass transition temperature of the polymer and compressing the mixture above the glass transition point of the polymer. In preferred embodiments, the polymer is an ethylene-vinyl ester copolymer of the general formula . . ."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:65-4:39 ("In a presently preferred embodiment, the polymeric materials useful for forming the matrix are the ethylenevinyl ester copolymers of the general formula . . ."); col. 9:40-10:17; col. 10:18-32.

Schiraldi '243: Col. 1:58-60 ("Other polymers that might be added are vinyl copolymers, polysaccharides, gelatin and collagen."); col. 2:30-51; col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 3:14-34; col. 4:67-

5:27; col. 10:3-7; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Helwing '868: Abstract ("The compositions may either be in capped form or leashed to a polymeric backbone. . . . The primary uses of the compositions are in controlled release applications such as drugs . . . or in any application where predictable hydrolytic release of the active agent is desirable."); col. 1:6-16 ("The present invention relates generally to compositions of matter and more particularly to covalently bonded compounds composed of active agents containing reactive functional groups The primary uses of the invention are in hydrolysable controlled release utilizations of active agents in such areas as pharmaceuticals, insecticides, herbicides, and the like."); col. 1:19-37 ("In addition . . . it may be highly desirable to have a system that permits the continuous controlled release of an agent . . ."); col. 1:38-2:11 ("One of the most common methods of achieving predictable controlled release mechanism of an active chemical agent is to encapsulate the agent with another material which gradually degrades in the desired medium. . . . A similar method is to trap molecules of the active agent within a surrounding polymer matrix. The matrix structure is such that exposure to an environmental material, usually water, causes the matrix structure to gradually degrade until the surrounding matrix structure is decomposed to the extent that the active agent molecule is permitted to escape into the environment. . . . The Heller, et al. patent utilizes a polymer structure . . . subject to hydrolysis, that is, it is subject to degradation in a gradual manner upon contact with water."); col. 2:12-24 ("The usefulness of structures such as that taught in Heller, et al. patent is significantly dependent upon the unique bioerodable, or hydrolysable, bonding structure . . ."); col. 2:25-37 ("The bonds so formed between the ketene acetals or vinyl ethers and hydroxyl groups are readily hydrolysable under even mildly acidic conditions. It is postulated that similar results will be obtained between various other functional groups on active agents and ketene acetals or vinyl ethers, and that these linkages will be hydrolysable with degradation of the covalent bond in the presence of water providing an ideal mechanism for controlled release of chemical or biological agents."); col. 38-53 ("In the present invention, as active agents will be bonded directly to the controlled release matrix, specific structural design of the base component system will most directly affect control over the hydrophobicity of the overall matrix."); col. 2:55-3:27; col. 3:37-43 ("It is an object of the present invention to provide an aggregation of useful chemical compounds wherein a chemically active agent via its polar active (PA) functional groups is covalently bonded with a carbonium ion mechanism ("CIM") base group, the bond therebetween being hydrolysable in a predictable manner, resulting in controlled release."); col. 3:47-50; col. 3:62-66; col.3:67-4:17 ("The present invention is an aggregation of compositions consisting of a hydrolysable covalent bond formed between a base structure and an active agent structure. . . . The combinations are particularly adapted for use in controlled release of the active agents by way of hydrolysis. The usefulness of the combinations of the present invention is found in a wide degree of chemical and biological applications including drugs . . ."); col. 4:18-38 ("The inventive compositions of matter have the common property that the covalent bond joining the active agent to the base component is predictably hydrolyzable."); col. 4:39-5:6; col. 5:7-46; col. 5:47-50 ("An advantage of the present invention is that new compositions of matter may be created which are subject to predictable hydrolysis under selected environmental conditions."); col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20 ("Each of the compositions of the present invention has two distinct moieties joined by a

hydrolyzable covalent bond. . . . The active component will have this chemical or biological effect when it is in its free molecular form but will not have the same effect when it is restricted in the inventive composition by the covalent bond. The hydrolytic decomposition of the covalent bond will act to release the agent so that it may again act in its original molecular form."); col. 7:21-8:50 ("Polymeric support substrates for the leashed systems would include polyvinyl alcohol, dextran, cellulose and similar polyhydroxy polymers."); col. 8:51-9:29 ("The common thread found in the various active agents is that each include one or more functional PA subgroups which are capable of forming the desired hydrolyzable covalent bond with the CIM subgroups of the base component in a predictable manner."); col. 9:30-52 ("With respect to other active agent functional PA groups and CIM base components, the bond structure will not be a pure orthoester linkage but will be of a similar hydrolyzable nature."); col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48 ("However, in the presence of water, the orthoester-type linkage is subject to hydrolysis as shown in equation EQ-2 and the Z group representing either the ketene acetal or thioacetal."); col. 12:49-13:5 ("The hydrophobicity of the inventive compositions may be altered such that the composition hydrolyzes at different rates."); col. 19:57 ("As is clear from the above, the scope of possible compositions that can be created according to the present invention is extremely broad. . . . All of the inventive compositions are such that they may be created by the process of the present invention and all will be similar in that the CIM and PA groups will form a hydrolyzable covalent bond which will act to keep the inventive composition intact under environmental conditions until hydrolysis occurs."); col. 20:18-37 ("Timed-release drugs for controlled introduction into the blood stream or other body tissues or cavities are well known, including compositions referred to as pro-drugs. The inventive compositions are extremely well adapted for use in this field. . . . Along these lines, the inventive systems could be used to deliver not only general drugs, but cancer drugs, hormones, vitamins, fungicides and even used as a more durable sunscreen."); col. 20:46-54; col. 20:55-68 ("The preferred embodiment of the present invention may also be applied to a surface as a film of uniform consistency for use in several areas of application. . . . The chemically linked nature of the controlled release matrix affords not only the ability to apply such films, but permits the most compact physical structuring possible in a controlled release matrix as well as an assured even distribution of the desired agent."); col. 21:27-41; col. 21:42-46 ("The composition of claim 1 wherein said covalent bond is predictably degradable via hydrolysis such that the active agent component may be released in a controlled release manner under selected environmental conditions."); col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3 ("The composition of claim 1 wherein the covalent bond is destructible via hydrolysis at a predictable reaction rate in a specified environment to yield a hydrolytically degraded base component and the active component as separate molecules."); col. 23:4-col. 24:27.

Valentini '029: Col. 3:15-25 ("The semipermeable nerve guidance channels of the present invention can also be biodegradable.").

Greco '135: Abstract; col. 1:19-26 ("This invention relates to methodology for the surface modification of surgical implants permitting the binding of drugs which, after implantation, are slowly released. More particularly, this invention relates to improved surgical implants having sustained, localized delivery of pharmacological agents such as extended antibiotic activity or reduced thrombogenicity, and methods for producing same."); col. 1:29-2:59 ("The surface modification of surgical implants by the adhesion of pharmacological agents

for the purpose of minimizing infection and prosthesis rejection is well-known and has generated broad interest for some time. . . . The present Application is therefore an effort to further disclose and particularize this aspect of the invention, i.e., the development of the antibiotic bonded prosthesis utilizing an anionic surfactant and the oppositely charged drug, antibiotic or other agent or factor."); col. 3:8-19 ("An object of the present invention is to provide improved surfactant-modified implantable devices having a drug, including antibiotics, antithrombogenic agents, thrombolytic agents, disinfectants, etc., bound to the surface thereof. . . . Another object of the present invention is to provide an improved implantable device having a drug bound thereto of improved release times."); col. 3:22-27; col. 3:30-43; col. 4:2-39; col. 5:30-6:58 (disclosing process by which antibodies can be bound to thermoplastic substrates); col. 7:46-9:3; col. 9:10-12.

Bawa '279: Abstract; col. 1:16-36; col. 2:27-35 ("With the foregoing and other objects in view, the invention herein provides a sustained-release polymeric hydrogel dosage form useful for topical, systemic or transdermal administration of a medicinal agent comprising one or more polymerizable hydrophilic polymers, an ion-exchange resin, a cross-linking agent and optionally one or more hydrophobic polymers."); col. 2:39-46; col. 2:47-68 ("The preferred hydrophilic monomers are the hydroxyalkyl esters, specifically hydroxyethyl methacrylate (HEMA)."); col. 4:14-25; col. 6:40-44 ("The invention contemplates a variety of processes for preparing the sustained-release polymeric hydrogel dosage form whereby the medicinal agent is retained by the polymeric matrix and, upon tissue contact, is gradually released into the tissue."); col. 7:15-21; col. 8:1-6; col. 8:29-49; col. 8:54-55; col. 8:66-68; col. 11:42-54; col. 13:10-17; col. 13:26-14:14.

Aebischer '627: Col. 3:23-49 ("In addition, these polymeric materials have the capacity for sustained release of the embedded substance at a controlled rate."); col. 3:57-4:3 ("The polymeric insert includes pores having a molecular weight exclusion of from about 1 kD to about 1,000 kD, but preferably from about 25kD to about 100 kD. In one preferred embodiment, the polymeric insert includes a hydrophobic matrix such as ethylene-vinyl acetate copolymer."); col. 6:52-59 ("the insert may be composed of any biocompatible material having the desired pore size and being composed of materials which do not limit the activity of the substance embedded therein. . . . [H]ydrophobic matrices such as ethylene vinyl acetate are particularly useful."); col. 7:3-12 ("One way of providing the source of neurotransmitter include incorporating it into the polymeric insert. The encapsulating material provides a protective environment for substances such as neurotransmitters or cell growth factors embedded therein, while affording sustained release of the substance at a controlled rate therefrom."); col. 7:13-28; col. 7:29-56 ("The release rate may also be controlled by the amount of pure, impermeably polymeric material coating the effector substance-embedded insert; the more (or thicker the) coatings, the slower the release rate. Materials such as polyurethane or pure ethylene-vinyl acetate are particularly useful for this purpose."); col. 10:31-34 ("To retard dopamine release, three coats of 10% EVAc were applied to each rod by repeated immersion . . ."); col. 14:29-32; col. 14:45-49; col. 14:57-58.

Wood '066: Abstract ("A controlled-release bandage containing therapeutic agents in a poly(vinyl alcohol) cryogel is disclosed. The bandage may include . . . hydrophobic particles to further insure controlled and constant release of therapeutic agents."); col. 2:56-66 ("Bandages comprising cryogel and therapeutic agents are used to provide a protective covering and to

provide a controlled and uniform administration of therapeutic agents to sites of trauma such as wound, thermal or chemical burns, ulcers, lesions or surgical sites. Cryogel bandages may include . . . particles having hydrophobic properties, which absorb the therapeutic agent and release it in an uniform and controlled manner."); col. 3:47-4:36; col. 7:6-32 ("The release of therapeutic agents from the bandage has been found to be further controllable by including insoluble particles capable of adsorbing or forming salts with the therapeutic agent in the bandage. . . . Other examples of suitable insoluble particles include hydrophobic resins, silica, hydroxyl apatite and aluminum oxide."); col. 7:43-50; col. 8:55-56; col. 26:8-18 ("The bandage of claim 1 wherein the insoluble particles capable of adsorbing or forming salts with the therapeutic agent are a hydrophobic resin particles.").

Strecker '746: Abstract; col. 1:63-2:2; col. 2:21-32; col. 3:5-17 ("Another sensible advanced version is characterized in that medications in the lining are dissolved in the wrapping material or included in the form of beads."), ("It can be practical for there to be more or less openings in the wall of the lining next to the lumen than there are in the wall next to the inner surface of the vessel. The ratio can be exploited to prescribe the dosage of medication to the lumen or wall of the blood vessel."); col. 3:17-26 ("The wrapping material can also to advantage be biodegradable When the material is biodegradable, the medication will be released not by diffusing out of the vehicle but by escaping as the vehicle that the medication is dissolved in or that accommodates the beads that encapsulate the medication at its surface decomposes and by accordingly coming into contact with body fluids."); col. 3:27-33; col. 5:10-12; col. 5:38-41; col. 6:1-17; col. 6:35-38; col. 7:16-37 ("a lining impregnated with medication for delivery to a wall of said body lumen"); col. 7:48-65; col. 8:19-10:19; Figs. 7 & 8.

Lambert '246: Abstract ("The biologically active compound is, therefore, released only at the site where it is desired, i.e., where the prosthetic article is positioned."); col. 1:46-55 ("Release of heparin from intravascular catheters in quantities sufficient to decrease thrombosis on the catheter has been achieved by either covalently bonding a charged molecule to a polymer or incorporating a large nonmobile charged molecule on the surface of the polymer . . ."); col. 1:57-61; col. 2:15-34 ("Increasing the lipid solubility of the compound slows release from the polyurethane, and increases the tissue retention. More lipid soluble compounds are, therefore, preferred agents for use in the practice of the present invention."); col. 2:38-40 ("In accordance with the present invention, there is provided a method for preparing a system suitable for localized delivery of biologically active compounds to a subject."); col. 2:40-49; col. 2:53-65; col. 7:31-33 ("The results of this example demonstrate that polyurethane stent coatings can concentrate and release lipophilic drugs in vitro."); col. 8:58-9:4 ("Adventitia overlying the stent contained 360 times the concentration of forskolin in the blood and 305 times the concentration of forskolin in the contralateral artery. . . . In a similar model, etretinate, a retinoic acid analog, develops concentrations in the media of 250 ng/mg tissue at 24 hours. At 24 hours, this concentration was over 2000 times the concentration in the blood."); col. 9:31-37 ("These data demonstrate that a polyurethane coated nitinol stent is capable of delivering a lipophilic drug in high local concentration in the vessel wall. The large 450 fold differential of local tissue levels of forskolin over blood levels reflects the capability of this delivery system to provide high local concentration and potentially higher efficacy, with lower risk of systemic side effects."); col. 10:47-50; col. 10:62-64 ("The drug delivery system of claim 1 wherein the biological agent is absorbed substantially throughout the entire thickness of the polyurethane elastomer coating.");

col. 11:16-17 ("The drug delivery system of claim 8, wherein said biologically active compound is a lipophilic compound."); col. 11:30-31; col. 11:36-40; col. 12:12-13; col. 12:17-21; col. 12:53-54.

Bellamkonda '029: Col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 5:32-48 ("The agarose hydrogels of this invention may be used as a carrier to present various ECM proteins or peptides We prefer covalent immobilization of ECM proteins to the hydrogel backbone."); col. 7:26-32 ("In a preferred embodiment, laminin-derived oligopeptidic fragments . . . are coupled to the hydroxyl backbone of agarose, using any suitable method."); col. 9:36-48 ("These growth factors may be incorporated into the channel membrane . . ."); col. 11:7-8 ("Additionally, the membrane may be composed of a biodegradable material."); col. 11:41-50; col. 12:13-16 ("Preferably the permselective membrane is fabricated to be impermeable to some of these substances so that they are retained in the proximity of the regenerating nerve ends."); col. 12:42-49; col. 12:50-56; col. 15:67-16:17; col. 23:54-24:55.

Dayton '382: Abstract ("The stent is then coated with a polymer . . . which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids, with the equilibrium being controlled by charge distribution, concentration and molecular weight of the bioactive substance in relation to the pore size of the polymeric carrier for controlled prolonged release of said bioactive substance."); col. 1:9-17 ("The present invention relates to an improved percutaneously inserted endoprosthesis device which is permanently or temporarily implanted within a body vessel, typically a blood vessel. More particularly, the present invention relates to a new procedure for administering localized bioactive substances via prosthesis designs . . ."); col. 3:36-39; col. 3:62-4:17 ("Among these polymers are polymers having a microporous structure, such as . . . biodegradable polylactic acid polymers, polyglycolic acid polymers . . ."); col. 4:24-33 ("A bioactive substance is preferably admixed in the polymer for elution from the microporous structure of the stent or coating on the stent after implantation. The rate of elution of the bioactive substance is controlled by selecting a pore size for microporous structure . . ."); col. 6:64-7:7 ("Also included in the polymer is a bioactive substance having a charge distribution, concentration and molecular weight selected which achieves an equilibrium in relation to the pore size of the polymeric carrier with said surrounding body tissues or fluids."); col. 7:8-14; col. 7:20-23.

Burt '036: p.4:19-33 ("Within one aspect of the present invention, compositions are provided . . . comprising (a) an anti-angiogenic factor and (b) a polymeric carrier. A wide variety of molecules may be utilized within the scope of the present invention as anti-angiogenic factors Similarly a wide variety of polymeric carriers may be utilized, representative examples of which include poly(ethylene-vinyl acetate) . . . and copolymers of polylactic acid and polycaprolactone."); p.10:17-25; p.14:9-27; p.21:2-4; p.51:1-52:35.

Goldin '568: Abstract; col. 1:21-34 ("In certain circumstances, another desirable use of controlled release methods is to target the delivery of a therapeutic agent specifically to the tissue or site that can benefit from the presence of such an agent."); col. 1:35-41 ("Several classes of controlled release strategies have been developed, principally involving: (a) release by controlled diffusion; . . . and (c) release limited by chemical control of the interaction of the agent with a substrate to which it is adsorbed or bound."); col. 1:43-62 ("Release by controlled diffusion may be accomplished by means of containment of the therapeutic agent within a substrate whose small pore size and/or tortuosity of diffusion path thereof limits the diffusion of said agent through the substrate. . . . The therapeutic agent can be incorporated within the diffusion-limiting substrate Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:8-16 ("Towards that end, diffusion-controlled slow release devices have been fabricated from biodegradable polymers . . ."); col. 2:24-28; col. 3:42-53 ("Release by chemical control most commonly involves chemical cleavage from a substrate to which a therapeutic agent is immobilized, and/or by biodegradation of the polymer to which the agent is immobilized."); col. 3:54-65 ("Another variant of release by chemical control termed herein "controlled noncovalent dissociation or 'CND'", relates to release resulting from dissociation of an agent that is bound temporarily by non-covalent binding of the agent to a substrate."); col. 4:25-45 ("The microskin is specifically tailored to bind macromolecules . . . noncovalently by cooperative secondary bonds, and slowly release the macromolecules by controlled non-covalent dissociation (CND)"); col. 4:63-66; col. 6:1-19 ("Because preferred embodiments of the CND controlled Release Device and methods of use thereof employ membranes whose pore size is normally much greater than molecular dimensions, the kinetics of release are governed primarily by the strength and number of the reversible cooperative secondary bonds which immobilize said protein for CND."); col. 6:20-29 ("Limitation of the toxicity associated with the macromolecules to be released results from selective delivery to the site of action in the amounts and at the time needed. While in practice, the temporal and spatial selectivity of the current invention may not be absolute, it is clearly an improvement over more conventional modes of delivery . . ."); Fig. 1A; Fig. 1B; col. 8:65-9:6; col. 9:18-22; col. 9:23-30; col. 9:43-50 (" . . . delivery from controlled release devices can be controlled by diffusion out of said device, dissociation of chemical bonds, and the like."); col. 9:51-55; col. 10:45-54; col. 17:40-54 ("[S]ynthetic polymers . . . may be derivatized to attach functional groups which may react under appropriate circumstances to form covalent bonds with the macromolecules one wishes to bind and release in a controlled manner."); col. 20:9-12 ("By appropriate use of said Device, one can selectively target a therapeutic site . . ."); col. 20:46-21:19 ("[W]hen the pore size of the underlayment and/or the microskin approaches submicron dimensions and/or the thickness of said Devices approaches millimeter dimensions or greater, diffusion of the agent to be delivered out of said device may contribute to or even be the predominant process governing controlled release from said Device."); col. 21:47-49 ("A coating of a permeable guide tube, with a secondary membrane designed to exclude macromolecules from without."); col. 27:10-18; col. 32:26-31.

Palmaz '762: Col. 10: 28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '337: Col. 9: 24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Zaffaroni '254: col. 2:6-9 ("Still another approach has been to enclose the drug within a single capsule having a polymeric wall or walls through which the drug can pass, for example, by diffusion."); col. 2:16-26 ("Additionally, these prior art devices have generally been based on the use of a single material, such as silicone rubber polymers, especially polydimethylsiloxane, as the diffusion control membrane. In large part, these polymers were selected because of their permeability to some important drug molecules. But, it has been found that mere high permeability without consideration of release rate controlling properties can be a significant disadvantage which defeats the primary object of an acceptable drug delivery device."); col. 4:54-58 ("In operation, solid drug carrier 13 serves as a reservoir 12 by supplying dissolved drug 14 to the micropores 15 of wall 11 as drug molecules move through the carrier to bathe the inner surface of wall 11."); col. 7:18-25.

Langer I: p.29 ("In the bioerodible system, the drug is distributed relatively uniformly throughout the plastic as in matrix systems, but it differs from the matrix in that its plastic portion decreases with time. As the plastic surrounding the drug is eroded, the drug escapes. . . . The most popular bioerodible polymers have been absorbable suture materials such as polylactic acid."); p.29-30 ("The second type of chemically controlled system is known as a pendant chain system. In simplest form, the drug is attached via chemical bonds to a polymer backbone. It could also be attached via a spacer group Release occurs when water reacts to break those bonds, thereby freeing the drug. Release rates are adjusted by varying the hydrophilicity of the polymer backbone. Systems could also be designed so that an enzymatic reaction could break the drug-polymer bonds."); p.29 Figure legend ("Chemically controlled pendant chain drug-delivery system. Here, the drug is bound to a polymer backbone and released by hyd[r]olytic or enzymatic cleavage, the key to controlling the medication's delivery.").

Langer II: p.217-18 ("In chemically controlled systems, release is accomplished either by biodegradation of the polymer . . . or by chemical cleavage of the drug from a polymer backbone to which the drug had been bound as a pendent group."); p.218 Fig. 3; p.219 Fig. 4 ("Chemically controlled pendent-chain drug-delivery system. Here, the drug is bound to a polymer backbone and released by hydrolytic or enzymatic cleavage."); p.221-225 ("Contraception" "Immunization" "Anticoagulation" "Cancer" "Insulin Delivery" "Controlled-release formulations may be applied to other clinical areas, including the release of narcotic antagonists, antibiotics, interferons, anesthetics, anti-arrhythmics, and antimalarial drugs.").

Langer III: p.25 ("Matrix Systems"); p.26-27 ("From a chemical standpoint, Heller has considered bioerodible systems in terms of three dissolution mechanisms: [1] water-soluble polymers insolubilized by degradable cross-links; [2] water-insoluble polymers solubilized by hydrolysis, ionization, or protonation of pendant side-groups; and [3] water-soluble molecules. These mechanisms represent extreme cases, and erosion by a combination of mechanisms is possible."); Fig. 3-3; Fig. 3-4; p.27-28 ("In pendant chain systems, a drug is chemically bound to a polymer backbone-chain and is released by hydrolytic or enzymatic cleavage. . . . The polymer

system can be either soluble or insoluble . . . insoluble forms are more desirable for long-term controlled-release implants. The backbone may also be biodegradable or nonbiodegradable. . . . The drug itself can be attached directly to the polymer or attached via a spacer group. The spacer group may be used to affect the rate of release and hydrophilicity of the system.").

Langer & Peppas: Fig. 5; p.80-83 ("Matrix Systems"); p.83 ("Polymers for Diffusion-Controlled Systems"); p.84; p.85 ("Ethylene-vinyl acetate (EVAc) copolymers have found major applications in controlled release of bioactive agents because of their relatively good chemical stability, biocompatibility, and inertness."); Fig. 7; p.86-87 ("Chemically controlled drug release generally involves one of two types of systems: 1) Erodible systems in which the drug is dispersed in a biodegradable polymer and drug release is influenced by the rate of degradation of the polymeric material, and 2) pendant chain systems in which the drug is attached to a polymer through a hydrolytically or enzymatically labile linkage. Drug release is influenced by the rate of degradation of this linkage."); Fig. 8; p.87-100 (describing and identifying polymers for biodegradable drug release systems); p.100-101 ("In [pendant chain systems] a drug is chemically bound to a polymer backbone and is released by hydrolytic or enzymatic cleavage. . . . [I]nsoluble [backbones] are more desirable for long-term controlled-release implants. . . . The drug itself can be attached directly to the polymer or it can be attached via a spacer group. The spacer group may be used to affect the rate of release and hydrophilicity of the system. To achieve near constant release, the cleavage of the drug from the polymer must be the rate-limiting step. . . . There has recently been interest in developing controlled-release systems using pendant chain polymers for clinical applications."); p.114-16 ("Medical applications of controlled-release systems can be divided into four general areas: oral systems, transdermal systems, external implants, and subcutaneous implants.").

Langer IV: p.36 ("In matrix systems, the drug is uniformly distributed through a polymer."); Fig. 2; p.37 ("Two systems of chemical control exist. The first mechanism is bioerosion or biodegradation of the polymer. As the polymer surrounding the drug is eroded, the drug escapes. . . . The second type of chemically controlled system is known as a pendant chain system. In simplest form, the drug is attached via chemical bonds to a polymer backbone. It could also be attached via a spacer group. Release rates are adjusted by varying the hydrophilicity of the polymer backbone. Systems could also be designed so that an enzymatic reaction could break the drug-polymer bonds."); p.37 Fig. 3 ("Idealized diagram of the cross-section of a cylindrical or spherical bioerodible matrix."); p.37 Fig. 4 ("Idealized diagram of a chemically controlled pendant chain drug delivery system. The drug could be connected to the polymer backbone as shown or could be coupled to a spacer group attached to the polymer backbone."); p.41-42 ("The second type of [contraceptive] system is a subdermal implant composed of a biodegradable polymer."); p.44 ("Small (0.3 mm³) injectable pellets of ethylene-vinyl acetate copolymer containing 100 ug of a test antigen, bovine serum albumin, were positioned subcutaneously in mice.").

Langer V: p.24 (" Examples of polymers with these properties include nondegradable polymers such as ethylene-vinyl acetate copolymers (EVAc), and biodegradable polymers such as polylactic or polyglycolic acid.") ("Theoretically, the [biodegradable] polymers should have a hydrophobic backbone, but with water-labile linkage.").

Langer VI: p.115 (One approach that has received increasing attention as a means of prolonging drug release has been the incorporation of drugs in solid polymers (e.g., silicone rubber, ethylene-vinylacetate copolymer). This method permits drugs to be released for long time periods in a controlled fashion."); p.120-124 ("The ideal [biodegradable] polymer would have a hydrophobic backbone, but with water labile linkage.").

Laurencin & Langer: Fig. 2; p.304-306 ("Matrix Systems"); p.306-307 ("Three dissolution mechanisms for bioerodible polymeric devices are found in general: Type 1: water soluble polymers that are made insoluble through crosslinks that are degradable. On exposure to an aqueous environment, crosslinks are broken, polymer dissolves, and release occurs. Type 2: water insoluble polymers that on exposure to an aqueous environment are solubilized by hydrolysis, ionization, or protonation of pendant side groups. Type 3: water insoluble polymers containing hydrolytically unstable backbone linkages. On exposure to an aqueous environment, polymer chains are cleaved to small water soluble monomers."); p.307 Fig. 4; p.308-309 ("In [pendant chain systems], drug is chemically bound to the backbone of a polymer. Release takes place by hydrolytic or enzymatic cleavage. . . . Polymer systems can be soluble or insoluble, and the backbone itself may be bioerodible or nonbioerodible. Soluble backbone chains are generally used for transport functions such as cell targeting; insoluble forms are more desirable for long-term controlled release implants. Drug can be chemically attached to the polymer directly or through a spacer group. The spacer group may be used to affect the rate of release or hydrophilicity of the system."); p.308 Fig. 5 ("Chemically controlled pendant chain drug delivery device. Drug bound to polymer backbone is released by hydrolytic or enzymatic cleavage."); p.313-316 (clinical applications of EVAc and biodegradable polymers).

Langer VII: p.1529 ("Chemical control is accomplished either by polymer degradation or chemical cleavage of the drug from a polymer."); p.1529 Fig.1(B), (C) and (D); p.1530 ("Examples of polymers that perform in this way are non-degradable ethylene-vinyl acetate copolymer and degradable lactic acid-glycolic acid copolymers."); p.1531-32 ("Theoretically, the [ideal surface-eroding] polymer should be hydrophobic but should have water-labile linkages.").

Langer & Moses: p.341-42 ("[W]e proposed that an ideal polymer would have a hydrophobic backbone, but with a water labile linkage."); p.342-44 ("One such report . . . employed the porous ethylene-vinyl acetate copolymer (EVAc) system to provide sustained release of fibroblast growth factor (FGF) or epidermal growth factor (EGF).").

Chien: p.32-33 ("[The hydrolysis-activated] controlled drug delivery system depends on the hydrolysis process to activate the release of drug molecules. . . . The release of a drug from the polymer matrix is activated by the hydrolysis-induced degradation of polymer chains and controlled by the rate of polymer degradation.") ("[The enzyme-activated] controlled drug delivery system depends on the enzymatic process to activate the release of drug. . . . The release of drugs is activated by the enzymatic hydrolysis of the biopolymers by a specific enzyme in the target tissue."); p.37 ("An ideal site-targeting drug delivery system has been proposed . . . constructed from a nonimmunogenic and biodegradable polymer backbone having . . . a drug moiety that is covalently [sic] bonded to the polymer backbone through a spacer and contains a cleavable [sic] group that can be cleaved only by a specific enzyme(s) at the target tissue.").

Thomson: p.34-36 ("The degradation of synthetic polymers is, in general, brought about by simple hydrolysis, although in some cases enzymatic processes assist in the degradation mechanism.").

Hanes & Langer: p. 647 ("Polymers can also be used to deliver vaccines in a controlled manner."); p.648 ("Biodegradable polymeric devices or pendant chain systems are examples of chemically controlled devices. In the former, molecules are typically dissolved or entrapped in a biodegradable, bioresorbable polymer matrix As the polymer degrades and erodes, molecules are released to the surroundings. In pendant chain systems, molecules are chemically attached to the backbone of a polymeric carrier using hydrolytically or enzymatically degradable bonds. In this case, the molecules are liberated as the bonds holding them to the polymer are cleaved."); p.649 Fig. 29.2; p. 652 ("For the present development of vaccine delivery systems, the use of biodegradable polymers presents significant advantages over the use of nondegradable systems."); p.654-55 ("There are many such polymers that may prove useful for controlled delivery of vaccines; however, no degradable polymer systems has been more widely studied with respect to release kinetics than the lactide/glycolide polyesters."); p.655-56; p.656-58 ("Advantages of Controlled Release for Immunization").

Batz: p.26-27 ("Based on their chemical structure polymeric drugs are divided into the following three groups b) Drugs in which the active substance of known biological activity is bound to a polymeric carrier molecule via a functional group."); p.36-43 ("Polymeric drugs formed by covalent bond of known active components to soluble macromolecular carriers"); p.48 ("Polymeric Forms of Deposit Without Covalent Bond Between Drugs and Polymeric Materials.").

Donaruma: p.10 ("Allan, Chopra, Neogi, and Wilkins, in studies concerned with the design and synthesis of controlled release pesticide polymer combinations, investigated the duration of effectiveness of various herbicidal phenoxyacetic acids chemically bound as pendant substitutes to natural or synthetic water-soluble and water-insoluble polymers."); p.17, 19-20 ("[I]t can be seen that in some cases portions of the polymer repeat unit are structurally constituted so that by hydrolysis the polymer chain or a pendant group may be sundered by hydrolysis. . . . Chemically combining a drug in a polymer may offer a means of sustained release and/or prolonged activity of drugs and/or drug latention. These are not new concepts, and examples are reported in the literature.").

Harris I: p.334 ("As reported in this review, our work has involved the syntheses and evaluation of polymers containing pendant aquatic herbicides."); p.344 ("The herbicide release rates of polymers containing herbicides as pendant substituents are extremely slow in water with pH=C at 30°C. The herbicide release rates, however, can be increased by incorporating hydrophilic groups along the polymers' backbones").

Feld: p.113-15 ("One approach to obtaining these formulations has been the synthesis of polymers that contain pesticides as pendent side chains. . . . Pesticide release occurs by the slow, sequential hydrolysis of the pesticide-polymer chemical bonds. This provides a sustained release of the pesticide over an extended period of time. The actual release depends on the nature of the pesticide polymer bond and the dimensions and structure of the resultant macromolecular

combination."); p.116-17 ("It was postulated that increasing the length of the pendent side chain would enhance the hydrolysis of the herbicide-polymer bond."); 117-19 ("Herbicide reactivation was produced enzymatically using lipase, acetylcholinesterase and trypsin.").

Harris & Post I: p.622 ("One approach to obtaining controlled-release pesticide formulations that contain a high percentage of pesticide has been the synthesis of polymers that contain pesticides as pendent side chains. The pesticide is presumably released by the slow sequential hydrolysis of the pesticide-polymer chemical bonds. . . . It was postulated that increasing the length of the pendent side chain would enhance the hydrolysis of the herbicide-polymer bond.").

Harris & Post II: p.225 ("One approach to obtaining controlled-release pesticide formulations that contain a high percentage of pesticide has been the synthesis of polymers that contain pesticides as pendent side chains. The pesticide is presumably released by the slow sequential hydrolysis of the pesticide-polymer chemical bonds. . . . It was postulated that increasing the length of the pendent side chain would enhance the hydrolysis of the herbicide-polymer bond.").

Drobnik: p.2833 ("Water-soluble copolymers based on poly[*N*-(2-hydroxypropyl)methacrylamide] and bearing in their side chains a chromogenic substrate for chymotrypsin were prepared by direct copolymerization or polymeranalogous reaction."); p.2834 ("The bonding of drugs onto macromolecules is an old idea, because it offers a potential optimization of the pharmacokinetics of drugs. The majority of pharmaceuticals are inactive in the macromolecular form and must, therefore, be released in their original active low-molecular weight form, i.e. their attachment to the polymer must be reversible, or degradable."); p.2844-47 ("The results also indicate the general influence of the spacer: the longer the spacer, the easier the cleavage of the enzyme susceptibility bound For practical purposes, that is, enzyme-specific binding of drugs to polymers, the following conclusions can be drawn from the above results . . .").

Allan I: p.17 ("These materials are chemical or physical combinations of known and established pesticides with macromolecules. . . . As the pesticide-polymer combination lies in the soil, a gradual decomposition occurs, and the pesticide is slowly released over the desired and predictable period of time."); p.18-19 ("This situation is avoided by the use of a chemical combination of the butyric acid [herbicide] with the polymeric components of bark. The ester linkage joining the herbicide to the bark will not be easily attacked by any β -oxidase and the butyric acid herbicide is thereby stabilized. Essentially, the only butyric acid herbicide available for β -oxidation is that continuously being released from the bark. This release will occur whether the combination lies in or on the surface of the soil since attack by moisture, micro-organisms and the weather can occur in either of these zones.").

Allan II: p.349 ("We have therefore investigated the potential of pesticide-polymer combinations as a means of securing controlled release of a biodegradable pesticide in approximately the correct amount needed over an appropriate period of time. . . . Two distinct approaches are not reported. (a) Pesticide release by diffusion through polymers, and (b) pesticide release by degradation of a polymer containing the pesticide as a pendent side chain. . .

. For case (b) the pesticides . . . are chemically attached as a pendent substituent to a natural or synthetic water-soluble or insoluble polymer . . ."); p.350 ("In the biological environment, side chain degradation occurs so that the chemical bonds holding the pesticide within its polymeric prison are sequentially broken to provide a sustained release of the pesticide over an extended period of time. The rate of release will clearly be determined by the nature of the pesticide-polymer bonds, the chemical characteristics of the pesticide and polymer and the dimensions and structure of the resultant macromolecular combination.") ("Although developed for developed for forest pest control the systems described should be broadly applicable to the controlled release of other biologically active substances.").

Allan III: p.173: ("Controlled release from polymeric matrix"); p.173-74 ("Representative of the other end of the thermodynamic spectrum is the situation where the pesticide is firmly attached to the substrate by a high energy covalent bond. Release of the pesticide then involves the cleavage of a definite identifiable chemical bond such as an ester or amide. . . . The simplest [arrangement] has the pesticide attached as a pendent substituent to a natural or synthetic water-soluble or insoluble polymer having a replaceable hydrogen The chemical bonds holding the pesticide within its polymeric prison are sequentially broken to provide a sustained liberation of the pesticide over an extended period of time."); p. 176 ("Moreover, the [controlled release] concept is broadly applicable to the release of other biologically active substances.").

Jakubke: p. 281 ("Observations in our laboratory indicated that an enzymatic cleavage of carrier-bound biologically active substance of low molecular weight is fundamentally possible. As part of a general model study of enzymatic reactions with insoluble substrates we investigated the α -chymotrypsin-catalyzed hydrolysis of Sepharose-bound L-phenylalanine 4-nitroanilide. As a spacer, 1 or 2 mol of 6-amino-hexanoic acid, respectively, were inserted between the gel matrix and the low-molecular weight substrate."); p. 282 ("The course of hydrolysis was proportional to time during the first 15 min. About 70% of total bound (ϵ Ahx)₂-Phe-NA was hydrolyzed after 4 hr."); Fig. 2 ("Dependence of hydrolysis on the enzyme concentration at 25°C."); p. 283 ("In agreement with this the substrate dependence of the hydrolysis rate shows the same course as observed with Glt-Phe-NA.").

Engelberg & Kohn: p. 292 ("For example, degradable polymers are now being investigated as intra-luminal grafts, stent-like devices that are implanted into coronary arteries in an attempt to prevent the collapse and the reblocking (restenosis) of blood vessels after successful balloon angioplasty."); p.293 ("Since surface-eroding, slab-like devices tend to release drugs embedded within the polymer at a constant rate, poly(ortho esters) appear to be particularly useful for controlled release drug delivery. It is not surprising that there are a significant number of publications describing the use of poly(ortho esters) for drug delivery applications."); p. 293-94 ("PLA, PGA and their copolymers are also being intensively investigated for a large number of drug-delivery applications. . . . PLA, PGA and their copolymers are currently the most widely used synthetic degradable polymers in human medicine."); p.294, Table 1; 294-95 (The potential applications of these [PHB polymers] include biomedical applications such as controlled drug release . . ."); p.295 ("Later, it was discovered that PCL can also be degraded by a hydrolytic mechanism under physiological conditions. Under certain circumstances, cross-linked PCL can be degraded enzymatically, leading to

enzymatic surface erosion."); p.296 ("It is interesting to note that despite its versatility, PCL has so far been predominantly considered for controlled-release drug-delivery applications.") ("[The low hydrolytic stability] was later recognized as a potential advantage by Langer et al. who suggested the use of polyanhydrides as degradable biomaterials."); p. 297; p. 298 ("Poly(ortho esters)"); p. 298-99 ("PGA"); p. 299 ("PLA"); p. 300 ("PBH and copolymers with HV"); p. 301 ("PCL") ("Because of their low mechanical strength and high hydrolytic reactivity, the two polyanhydrides tested appear to be limited to drug-delivery applications."); p. 302.

Roseman & Mansdorf: p. 91-105 ("The objective of this chapter is to describe the development of a bioerodible polymer implant that would release an incorporated drug by zero-order kinetics for at least 6 months. A further objective is the development of a system where drug release and polymer erosion take place concomitantly so that no polymer remains when the drug is depleted."); p. 107 ("There have been, however, studies where polymer-drug complexes have been synthesized, the major objective of which was to provide a controlled or prolonged action of the drug by the natural hydrolysis or biological scission of the covalent polymer-drug bond. In this way, mescaline, insulin, salicylic acid, D-isoproterenol, naloxone, plant cytokinins, 2,4-dichlorophenoxyacetic acid, norethindrone, and cortisol-21-acetate have been attached to and released from various synthetic and natural polymers through covalent bonds such as amide, ester, aso, carbamate, carbonate, oxime ester, and hydrazone."); p. 108 ("GAGs are biodegradable by enzymatic means normal to the host."); 108-109 ("We have taken advantage of various types of functional groups available on the GAG backbone (carboxyl, primary and secondary hydroxyl, and sulfate) in preparing and testing a series of complexes in which the drug was bound directly to the polymer or via an intermediate linking group such as an amino acid or other such bioacceptable entity. . . . Current work with other drugs bound to the GAG backbone by the same and different bond types (i.e., carbamate, ionic) will be reported in the near future."); p.110; p. 111 ("Amide and ester bond types were chosen because both are susceptible to chemical hydrolysis and both are prevalent naturally and thus are potentially dependable by enzymes."); p. 112 Fig. 2 & 3; p. 112-113 ("The release was pseudo-first order with a release rate constant of 0.10 day^{-1} and a half-life of 3.8 days. This is what one would expect if the rate-determining stem for release is the chemical hydrolysis of the ester bond in the prodrug."); p. 113 ("Reactions on polymers, such as the hydrolytic cleavage of GAG-drug bonds, has been shown to be affected by polymer chain length and conformation, steric isolation, and neighboring group effects."); p. 114; p. 115 ("Even though the amid bond between the drug and the polymer may hydrolyze slowly over this period and release cysteine, the rate-determining step for release was probably enzymatic breakdown of the complex. . . . A large advantage of using glycosaminoglycans as drug carriers is that they are biocompatible and biodegradable."); p.116 ("Chloramphenicol-GAG ester complexes released Cpl quickly by scission of the ester bon. Cysteine-GAG amide complexes degraded much more slowly and probably through enzymatic hydrolysis of the polymer or polymer-drug bond."); p. 117 ("Nevertheless, this concept provides an interesting base from which to design a drug release system; the rate of release may in principle be engineered by the judicious choice of drug-GAG bond based on the hydrolytic stability of the bond.").

Lee & Good: p. 2; p. 2-3 ("As a result of research ion improved absorbable sutures, poly (lactic acid), poly (glycolic acid), and lactic/glycolic acid copolymers, which hydrolyze to natural metabolites, have been developed for drug delivery purposes."); p. 3 ("[P]olymer erosion

can be controlled by the following three types of mechanisms: (1) water-soluble polymers insolubilized by hydrolytically unstable cross-links; (2) water-insoluble polymers solubilized by hydrolysis, ionization, or protonation of pendant groups; (2) hydrophobic polymers solubilized by backbone cleavage to small water soluble molecules. . . . [O]ther commonly used bioerodible/biodegradable polymers include polyorthoesters, polycaprolactone, polyaminoacids, polyanhydrides, and half esters of methyl vinyl ether-maleic anhydride copolymers.") ("Drug-Polymer conjugates. This system involve drug molecules chemically bounded to a polymer backbone. The drug will be released through hydrolytic or enzymatic cleavage. . . . The attachment of drugs to macromolecular carriers alters their rate of excretion from the body and provides the possibility for controlled release over a prolonged period. . . . Both natural polymers such as polysaccharides and synthetic polymers such as polylysine, polyglutamic acid, polyphosphazenes, copolymers of vinylpyrrolidone, copolymers of 2-hydroxypropylmethacrylamide, and etc. have been used as drug carriers."); p. 4 ("The drug-polymer linkage may be covalent, ionic, or through some weaker secondary molecular forces. The drug may be part of the polymeric backbone or attached to the side-chain either directly or through a spacer group. The spacer groups is generally selected in such a way that it may be hydrolyzed or degraded enzymatically under specific environmental conditions. Examples of such drug-polymer conjugates include the attachment of ampicillin, 6-amino-methacrylamide copolymers, methotrexate to poly (L-lysine), and norethindrone to poly(hydroxyalkyl)-L-glutamine. In addition to diffusion rate limitations as described in the next section, the drug release rate is primarily governed by the rate of cleavage of the drug from the polymer."); p.5- 7 ("Matrix Diffusion"); p. 7 ("Polymer Erosion. The release of a dissolved or dispersed drug from an erodible polymer matrix can be controlled by a variety of mechanisms ranging from hydrolysis/enzymatic cleavage as discussed in the previous section to swelling and dissolution."); p. 17 ("An important example of these processes is the controlled release of bioactive molecules from polymeric membranes. Many pharmaceutically active agents have been released at controlled rates from hydrophobic polymer carriers. . . . In 1976 it was demonstrated that hydrophobic polymers, in particular ethylene-vinyl acetate copolymer (EVAc), could be used to release molecules with molecular weights greater than 1000."); p. 182 ("Enzyme-Degradable Hydrogel"); p.188-200; p. 214-230.

Langer & Folkman I: p. 179 ("Therefore, we turned to other polymers such as ethylene-vinyl acetate copolymer . . ."); p. 180-83; p. 183-84 ("Poly(vinylalcohol), Hydron, and ethylene-vinyl acetate copolymer were examined for their ability to release soybean trypsin inhibitor . . ."); p. 185-88; col. 188-191 ("The following three studies demonstrate that the pellets are releasing macromolecules in biologically active form."); p. 191-92 ("The present experiments show that macromolecules with a wide range of molecular weights can be delivered in significant quantities from polymeric vehicles that are not inflammatory when implanted in animals. These polymers can release macromolecules in biochemically and biologically active form for periods in excess of 100 days as measured by direct assays. . . . The eventual clinical application of these polymers for delivery of macromolecules such as insulin, heparin, or enzymes may merit consideration.").

Langer & Folkman II: p. 798-99 ("Polyvinylalcohol, Hydron and ethylene-vinyl acetate copolymer were examined for the ability to release soybean trypsin inhibitor . . .")

("These studies show that sustained release of proteins and other macromolecules from polymeric vehicles can be achieved over prolonged periods.").

Langer VIII: p. 1 ("One approach that has received increasing attention as a means of prolonging drug release has been the incorporation of drugs in solid polymers (e.g. silicone rubber, ethylene-vinyl acetate copolymer). This method permits drugs to be released for long time periods in a *controlled* fashion."); p. 10 ("Controlled-release polymer formulations may also find applications in other clinical areas. One such area that has received increasing attention is the controlled release of antibiotics. . . . Polymers have also been used to deliver anesthetics, anti-malarial drugs, anticoagulants, and drugs to combat cardiac arrhythmia."); p. 27 ("However, several recent studies have demonstrated that matrix systems can be engineered to permit continuous release of large molecules. By solvent casting normally impermeable polymers such as ethylene-vinyl acetate copolymer in volatile solvents . . . along with powdered macromolecule, a series of interconnecting channels is formed within the polymer matrix. . . . These macromolecular delivery systems now open the possibility of delivering many important large molecular weight compounds such as insulin or interferon for prolonged periods."); Fig. 20; p. 28-29 ("[T]he volume of bioerodible systems becomes smaller with time, and, as the polymer surrounding the drug is eroded, the drug escapes."); p. 30 ("Erosion could be caused by hydrolytic or enzymatic cleavage of the crosslinks so that the ultimate degradation products are high molecular weight polymers. Alternatively, the degradation could occur in the polymer backbone so that the degradation products have low molecular weights."); p. 31-32 ("The third category of biodegradable systems are water-insoluble polymers that undergo hydrolytic or enzymatic backbone cleavage and are solubilized to small water-soluble molecules. . . . The best example of this class of polymer is polylactic acid or copolymers of lactic acid and glycolic acid."); p. 32 ("Sidman and coworkers . . . developed a peptide copolymer of glutamic acid and ethyl-*L*-glutamate."); p. 32-34 ("Pendant Chain Systems: In this type of system, a drug is chemically bound to a polymer backbone and is released by hydrolytic or enzymatic cleavage. The use of these therapeutic agents has received considerable attention in drug-related research. The major thrust so far has been the design of polymer-drug complexes for short-term use that can reduce toxicity, increase therapeutic efficiency, or be targeted towards specific cells or organs. . . . The drug itself can be attached directly to the polymer or it can be attached via a spacer group. The spacer group may be used to affect the rate of release and the hydrophilicity of the system. . . . To achieve near constant release, the cleavage of the drug from the polymer must be the rate-limiting step."); Fig. 22.

Langer & Folkman III: p. 114-15; p.117-18 ("Demonstration of Long-term Release") ("In initial trials with soybean trypsin inhibitor . . . protein was released . . . least rapidly from ethylene-vinylacetate copolymer."); p. 119-20 ("When tested in this fashion, ethylene-vinylacetate copolymer pellets continued to produce zones on these slides for over 100 days, indicating that the pellets were releasing nearly 1 ug/day or biochemically active protein."); p. 123-25 ("Insulin Delivery"); p. 125-26 ("Immunization Procedures").

Rhine: p. 265 ("Matrixes composed of ethylene-vinyl acetate copolymers are useful vehicles for the sustained release of macromolecules such as proteins These polymer systems had uniform drug distribution, and their release kinetics were reproducible."); p. 267 ("Therefore, macromolecules were added to a solution of polymer dissolved in a volatile solvent

(methylene chloride). This mixture, when cast and dried, produced matrixes capable of sustained macromolecular release. . . . The reproducibility of release kinetics for matrixes prepared by low temperature methods was demonstrated for different proteins and for a range of particle sizes and loadings."); p. 268 ("A coating can also be used to control macromolecular release kinetics."); p. 269 ("Clinically, these systems may prove valuable as single-step methods for immunization or for the continuous delivery of insulin and other high molecular weight drugs.").

Aebischer: p. 282-83 ("Chemically inert polymer matrices, allowing controlled release of entrapped macromolecules over long time periods . . . open a new avenue of investigation. . . . The solvents used appear to have no detrimental effects on the biological activity of a number of growth factors."); p. 283 ("Channel Fabrication"); p. 283 (disclosing the use of an impermeable outer coating which results in directional release of the treating factors into the lumen of the device); Table 1; p.286 ("The present study demonstrates that ethylene vinyl acetate copolymer can be fabricated into tubes with adequate physical properties for nerve entubulation and allows the controlled release of macromolecules.").

Langer IX: p.267 ("Two polymers suitable for sustained macromolecular release, poly(hydroxyethyl methacrylate), and alcohol-washed ethylene-vinyl acetate copolymer, were noninflammatory.") ("[W]e provide documentation that two polymers suitable for sustained macromolecular release, poly(hydroxyethyl methacrylate) (polyHEMA) and alcohol-washed ethylene-vinyl acetate copolymer, possess a high degree of biocompatibility in the rabbit cornea."); p.269; Table 1; p.276.

Langer X: p.179-80 ("Although we investigated several polymeric systems, the best results from the standpoint of tissue biocompatibility and long-term release (>100 days) were obtained with ethylene-vinyl acetate copolymer."); p.180 ("Biocompatibility studies"); p.181-87 ("In vitro and in vivo release kinetics"); p.192 ("Possible mechanisms of release of macromolecules") ("The absence of effect of ionic strength (fig7) suggests that osmotic pressure or charge interactions of drug with polymer have negligible roles in affecting release rates."); p. 195-200 ("Here, four studies exploring biomedical uses of these polymer systems are discussed. These include: (1) insulin delivery systems, (2) vehicles for immunization, (3) interferon delivery systems, and (4) systems for delivering anticancer or antiangiogenic macromolecules.").

Langer XI: p.95-96 ("Recent studies in our laboratory have demonstrated, however, that solvent casting of a variety of polymeric materials (ethylene-vinyl acetate copolymer, polyvinylalcohol, poly-2-hydroxymethyl-methacrylate) in the presence of powdered drug permits continuous release of macromolecules for over 100 days.").

Brown: p.1181 ("Macromolecules such as enzymes, antigens, and insulin have been released in biologically active form [from ethylene-vinyl acetate copolymers] for up to 6 months *in vivo*."); p. 1184 ("These data show that *in vivo* release can be accounted for by the same mechanisms operating *in vitro*; this should now make possible the further development and increased use of ethylene-vinyl acetate copolymer drug delivery systems.").

Kost & Langer: p.47-48 ("Bioerodible controlled systems."); p.48-49 ("Applications").

Hsu & Langer: p. 445-46 ("The current study shows the MW of EVAc copolymer is as important as drug loading and drug particle size in affecting the drug release kinetics. A release mechanism, which includes the properties of the polymer carrier, is proposed to serve as a guideline in selecting a suitable EVAc polymer carrier for a particular drug release device."); p.459.

Bawa: p.259 ("For example, EVAc polymers have been used as . . . delivery systems for insulin, interferon, and antigens."); p.263 ("Minimal effects exist due to osmosis or charge interaction of the drug with the polymer."); p.266 ("The data should be useful in the design of release vehicles for various polypeptides, polysaccharides, and other bioactive agents now produced by genetic engineering.").

Leong & Langer: p.202; p.203 ("The two common chemically controlled systems are a biodegradable matrix in which the drug is dispersed, and a polymer-drug conjugate in which the drug molecules are linked to the side chains of the polymer."); p.206-209 (describing use of biodegradable polymers for contraceptive systems); p.210-11 ("Against Ehrlich ascites carcinoma in rats, a sustained release of 5-fluorouracil from poly(ethylenevinylalcohol) is more efficacious than free drug administration."); p.211-14 ("Pendant systems"); p. 214-15 (use of EVAc for hormonal therapy and angiogenesis inhibition); 219-23 ("The clear demonstration of the feasibility [of sustained release of insulin from polymer] was later provided by a study using poly(ethylenevinylacetate) (EVAc).").

Baker: p.14-15 ("Diffusion-Controlled Monolithic Systems"); p.15-16 ("Biodegradable Systems"); 161-65 ("Poly(ethylene vinyl acetate)").

Langer XII: p.162 ("In chemically controlled systems, release is accomplished either by biodegradation of the polymer or by chemical cleavage of the drug from a polymer backbone on which the drug had been bound as a pendant group."); p.163 ("A variety of reservoir and matrix devices are prepared from swollen crosslinked hydrophilic polymers (hydrogels). Most successful devices of this kind are based on poly (2-hydroxyethyl methacrylate) (PHEMA) and related polymers although hydrophilic homopolymers of (poly vinyl 1-2-pyrrolidone) (PNVP), poly (vinyl alcohol) (PVA) and copolymers thereof have been tested with considerable success.") ("Ethylene-vinyl acetate (EVA) copolymers are prepared by emulsion copolymerization of ethylene and vinyl acetate. They are soluble in organic solvents and they can be used to prepare films or rods of dimensional stability and good mechanical strength."); p. 163-64 ("Biodegradable Polymers"); 164-67 (clinical uses for controlled-release polymer systems).

Langer XIII: p.166; p.170 ("Studies have also been conducted to explore numerous applications of these systems. These include release of insulin . . . , anti-calcification agents . . . , interferons . . . , growth factors . . . and inhibitors . . . , and neurologically active agents.").

Chasin: p.43-44 ("In designing a biodegradable system that would erode in a controlled heterogeneous manner without requiring any additives, we have suggested that due to the high liability of the anhydride linkage, polyanhydrides may be promising candidates."); p.45 ("Molding procedures"); p.47-62 ("Kinetics of Drug Release") (describing release of various compounds); p.66-68 (polyanhydride safety and clinical studies).

Langer XIV: p.538-40 (describing polymers used in controlled release systems, including cellulose, poly(glycolic acid) and poly(lactic acid), poly(ortho esters), polyanhydrides, silicone rubber, ethylene-vinyl acetate copolymer, and poly(2-hydroxyethyl methacrylate)); 540-42 (describing clinical uses for controlled release systems).

Brem: p.2 ("The ethylene-vinyl acetate copolymer (EVAc) is an example of a non-biodegradable polymer while poly[bis(p-carboxyphenoxy) propane-sebacic acid] copolymer (PCPP-SA) and the fatty acid dimmer-sebacic acid copolymer (FAD-SA) are examples of biodegradable polymers."); p.3 ("Clinical applications for the EVAc polymer include drug delivery for contraception, insulin therapy, cancer chemotherapy, glaucoma treatment, dental caries prevention, and asthma therapy."); p.4-6 (describing in vivo and clinical studies of PCPP-SA and EVAc based delivery of chemotherapeutic drugs).

Langer XV: p.102 ("Our best long-term release results were obtained with relatively hydrophobic polymers, such as ethylene-vinyl acetate co-polymer or lactic glycolic acid copolymer, using methylene chloride as a casting solvent."); p.105 ("Therefore, we proposed to initiate studies on the development of a new class of bioerodible polymers: polyanhydrides."); p. 109 ("Through the NH₂ groups of lysine, specific amino acid sequences such as arginine-lysine-aspartic acid (RGD) have been chemically coupled to polylactic acid-co-lysine.").

Thompson: p.31-32; p.32 ("In this article, we include hydrolysis and enzymatic degradation under the heading of biodegradative processes."); p. 32-33 ("Collagen is one of the most widely used and best characterized of the natural biomaterials"); p.33 ("Gelatin, cross-linked with formaldehyde, has been studied in vitro as a drug delivery matrix . . ."); p.33-34 ("Starch"); p. 34 ("Furthermore, because of its hydrophilicity, cellulose has been utilized in pharmaceutical formulations to enhance water uptake and improve drug delivery.") ("The degradation of synthetic polymers is, in general, brought about by simply hydrolysis, although in some cases enzymatic processes assist in the degradation mechanism."); p.35 ("Since . . . the degradation characteristics of [poly(glycolic acid)] are predictable and reproducible, PGA has become a material of choice for many proposed applications calling for a synthetic biodegradable polymer.") ("Poly(L-lactic acid)"); p. 36 ("Poly (ε-caprolactone)") ("[Poly(orthoesters)] have therefore been exploited as constant rate drug delivery devices.") ("Poly(anhydrides)"); p.36-41 ("Hydrophobic polymers") ("Poly(ethylene)"); p. 41-44 ("Hydrophilic Polymers") ("Poly(2-hydroxyethyl methacrylate)"); p.44 ("Natural and synthetic biodegradable polymers have been utilized in drug delivery and tissue engineering. Drug delivery systems based on biodegradable polymers facilitate the controlled release of drugs with the concurrent degradation of the polymer.").

Chandrasekaran: p.587 ("The simplest to a bioerodible drug delivery system is to disperse or dissolve the drug in a water-soluble polymer, which will slowly erode in an aqueous medium Another approach involves the synthesis of hydrophobic water-insoluble polymers in which the major fraction of the drug is released by erosion of the polymer matrix . . ."); p.588 ("Hydrophobic polymer solubilization can be achieved as a result of a chemical reaction that takes place at either a pendant group of the polymer or within the polymer backbone. When the reaction is confined to the pendant group, no backbone cleavage takes place, and one of the reaction products is a hydrolytically stable water-soluble polymer. . . . Hydrophobic polymers

can also be solubilized by an ionization reaction of pendant carboxyl groups; drug dissolution and release rate kinetics are obtained from partially esterified copolymers derived from ethylene-maleic anhydride or methyl vinyl ester-maleic anhydride.").

Kim: p194-96; Fig.4; 197-201 ("Drug Diffusion through Polymers"); p.202-204 ("Release Rate from Monolithic Devices"); p.204-206 ("Mechanistic Considerations of Drug Diffusion through Polymer Membranes"); p.215-220 ("Hydrophobic Polymers as Drug Carriers") ("Ethylene-Vinyl Acetate Copolymer (EVA)"); p.220-23 ("The synthesis of biodegradable polymers for controlled drug release is based on different strategies. 1. A degradable polymer medium to which a drug is dispersed. Here drug diffusion through the polymer matrix is influenced by the degradation of the polymeric material. 2. A degradable polymer medium to which a drug is attached through a hydrolytically labile linkage. Drug release is controlled by both hydrolysis of the drug from the polymer and by diffusion of the drug through the polymer matrix."); p.226-28 ("Design of Chemically Bound Polymer-Bioactive Agent (PBA) Systems"); p.228-29 ("Models of Chemically Bound Polymer-Bioactive Agent Systems."); p.229-46 ("Examples of Chemically Bound Polymer-Bioactive Agent Systems").

Dev: Abstract; p. 273 ("The purpose of this study was twofold: first, to test a polymer-coated removable stent system for local delivery of two lipid soluble drugs . . . and second, to compare these two drugs with respect to kinetics of their delivery to the arterial wall with the stent in place and their tissue washout rates after removal of the stent."), ("We used a commercially available biomedical grade polyurethane [as a stent coating]. . . . To study the kinetics of drug delivery, we used two lipid soluble compounds: forskolin and etretinate."), ("Ratio of peak drug levels in the vessel wall to those in the blood was 6,000 for etretinate and 780 for forskolin. . . . Polymer-coated stents could be used for local drug delivery to the vessel wall."); p. 274-75 ("the drug levels [of etretinate] in blood and the distant tissues are extremely low, and the ratio of local to systemic drug levels is very high (~6,000); p. 277 ("This [preferential release of drug into the arterial wall] may reflect slower diffusion of etretinate in the aqueous medium than forskolin or presence of significant tissue binding of etretinate.").

Claim 9 [9A]: The method of claim 8, whereby the layer permits the through passage of small molecules such that the device is non-toxic to the damaged tissue.

Where Found in the Prior References:

Schwartz '823: Col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference."); col. 3:64-4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or

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biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof.").

Scott '928: Col. 6:38-45 ("Also disclosed is a device comprising a stent encompassed by the sheath. The initial prototype is a sleeve of polymer, either degradable or non-degradable, that covers the entire stent (Fig. 3). Modifications of the polymer coating include a ring that encompasses the proximal portion of the stent, single or multiple strips that cover a portion of the stent, or a polymer coating with perforations.").

Tartaglia '113: Col. 1:64-2:2 ("The polymer material can be a thermoplastic or an elastomer, for example, so that the film can stretch or deform radially when the stent structural member is expanded. The film of polymer material can be formed as a solid sheet, or can incorporate holes of various sizes and shapes to promote rapid endothelialization."); col. 7:11-18 ("The polymeric film material also currently preferably includes a plurality of apertures so that the polymeric material is porous, to allow blood flow through the stent structural member to the vessel wall, such as for oxygenation and nutrient exchange to the vessel wall, and in order to present a decreased surface area for purposes of reducing thrombogenicity."); col. 8:58-65; col. 12:11-14.

Wolff '208: Col. 1:67-2:3; col. 27-29 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 6:59-63 ("The polymer may be biostable or bioabsorbable.").

Buscemi '450: Col. 4:28-44.

Ding '536: Abstract; col. 3:19-27 ("Another object of the invention is to provide a coating and process for coating a stent prostheses using a biostable hydrophobic elastomer in which biologically active species are incorporated within a coating."); col. 14:1-4 ("The device of claim 6 wherein the stent comprises a tubular body having open ends and an open lattice sidewall structure and wherein the coating conforms to said sidewall structure in a manner that preserves said open lattice."); col. 14:18-21; claim 14:35-38.

Hunter '981: Col. 17:63-18:7 ("[T]he anti-angiogenic compositions of the present invention may be formed as a film. . . . Such films are preferably flexible with a good tensile strength . . . and has controlled permeability."); col. 22:21-64.

Kowligi '782: Col. 1:18-26 ("The present invention relates generally to prosthetic vascular grafts for implantation within the vascular system of a patient, and more particularly, to a prosthetic vascular graft made from expanded, porous polytetrafluoroethylene (PTFE) tubing that is fabricated to retain the porous inner cylindrical wall of conventional PTFE vascular grafts, but wherein the outer cylindrical wall of the PTFE tube is rendered non-porous over at least a portion of its length"); col. 1:28-41 ("The use of implantable prosthetic vascular grafts made of expanded, porous PTFE is well known in the art. Such vascular grafts are often implanted just below the skin to provide blood access for long term hemodialysis."); col. 1:42-64 ("Expanded, porous PTFE material offers a number of advantages when used as a prosthetic vascular graft."); col. 2:38-52; col. 2:60-3:4 ("Alternatively, the non-porous elastomeric coating may be applied

over the outer cylindrical wall of the PTFE tube only along the first and second opposing end portions of the PTFE tube, and not along the central portion thereof. Such end-coating PTFE vascular grafts provide the aforementioned advantages of minimizing suture hole bleeding, increase suture retention strength, and preclude tissue ingrowth in the central portion of the vascular graft to help stabilize the same."); col. 3:35-38 ("Fig. 3 is a perspective view of an alternative embodiment of the present invention wherein only the opposing end portions of the PTFE vascular graft are rendered non-porous."); Figure 3; col. 4:1-5 ("The preferred starting material used for form PTFE tube 32 is expanded porous PTFE material of the type generally described within U.S. Pat. No. 4,187,390 to Gore. Such expanded, porous PTFE material is commonly used to form prosthetic vascular grafts."); col. 4:64-66; col. 10:18-24; col. 10:33-42.

Lambert '922: Col. 5:57-61.

Lambert '308: Page 10:17-21.

Myler '563: Col. 22:10-13; col. 3:53-55 ("Polymeric stents can be provided with relatively fluid impenetrable walls, or porous walls such as to allow drug delivery, as will be apparent to one of skill in the art."); col. 5:1-16; col. 5:39-41; col. 12:28-33.

Palmaz '417: Col. 11:22-26 ("Further, it may be desirable to have a plurality of openings 94 formed in coating 90, as shown in Fig. 5, whereby the fluid contained in body passageway 80 can be in direct contact with the dilated, or expanded body passageway area."); Fig. 5.

Schiraldi '243: Col. 2:30-43; 3:11-34.

Valentini '029: Abstract ("The guidance materials are chosen such that they are capable of allowing the diffusion of nutrients and other metabolites to the regenerating nerve site while excluding fibroblasts and other scar-forming cells."); col. 2:29-49 ("It has been discovered that the repair of severed or avulsed nerves can be greatly enhanced by the use of selectively permeable polymeric materials as nerve guidance channels. . . . The terms "semipermeable" and "selectively permeable" are capable of allowing the exchange of nutrients and other metabolites with the regenerating nervous tissue while excluding fibroblasts and other scar-forming cells. Preferable, the materials allow passage therethrough of solutes having a molecular weight of about 100,000 daltons or less."); col. 4:46-59; col. 5:13-32 ("The success rate and quality of peripheral nerve regeneration was dramatically enhanced through the use of a semipermeable material."); col. 5:42-6:12 ("The permselective characteristics of the inner membrane allow the exchange of nutrients, while concentrating growth factors released by the nerve and excluding scar-forming cells."); col. 6:14-24; col. 6:31-42.

Aebischer '627: Abstract; col. 3:57-4:3 ("The polymeric insert includes pores having a molecular weight exclusion of from about 1 kD to about 1,000 kD, but preferably from about 25kD to about 100 kD. In one preferred embodiment, the polymeric insert includes a hydrophobic matrix such as ethylene-vinyl acetate copolymer."); col. 4:11-27 ("The terms 'semipermeable' is used herein to describe biocompatible membranes that allow the diffusion therethrough of molecules having a relatively low molecular weight, while excluding the passage of those having a relatively high molecular weight. . . . The semipermeable membrane can be made of various polymeric compositions such as polyvinylchloride, polyacrylonitrile,

polyvinylidene fluoride, polystyrene, polymethylmethacrylate, polysulfone, and acrylic copolymers."); col. 7:57-8:14 ("In this embodiment, a semi-permeable membrane functions as a protective cell culture device for the neurotransmitter-secreting cells. The pores of the membrane should be large enough to enable the exchange of metabolites with body fluids, and to permit the diffusion therethrough of neurotransmitter produced by the cells therein, but are small enough to bar the passage therethrough of larger elements deleterious to the cells."); col. 13:31-48; col. 13:66-68; col. 14:22-28.

Strecker '746: Col. 3:41-50 ("It has also been demonstrated practical to ensure that once the prosthesis is in place the lining impregnated with at least one medication will be permeable enough for any metabolites that occur to enter the blood circulation through the wall of the vessel and for oxygen or nutrients for example to diffuse out of the blood through the lining to the wall of the vessel."); col. 3:51-62; Fig. 8; col. 6:50-55 ("The pores constitute radial channels of communication that allow the diffusion of metabolites between the wall and the lumen of the vessel."); col. 7:38-44.

Bellamkonda '029: Col. 2:65-3:5; col. 5:10-14 ("Several physical properties of the hydrogel matrices of this invention are dependent on gel concentration. Increase in gel concentration may change the gel pore radius, morphology, or its permeability to different molecular weight proteins."); col. 7:13-25; col. 10:28-40; col. 10:41-63 ("Permselective channels may support regeneration by allowing inward passage of nutrients and growth or trophic factors from the external host environment, while preventing the inward migration of scar-forming cells. . . . Appropriate choice of the molecular weight cut-off for the permselective channels will allow retention of laminin . . . within the nerve guidance channel."); col. 10:64-11:13; col. 12:17-25 ("Briefly, various polymers and polymer blends can be used to manufacture the nerve guidance channel."); col. 12:42-49; col. 19:7-16; col. 23:54-24:55.

Dayton '382: Abstract; col. 4:4-17; col. 4:24-33; col. 6:64-7:7 ("The polymer should have a microporous structure with a predetermined pore size."); col. 8:19-21; col. 8:66-9:5; col. 10:1-2.

Burt '036: p. 21:14-22:6.

Goldin '568: Col. 1:43-62 ("Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:24-29 ("Microporous membranes for release of proteins by controlled diffusion have been fabricated from ethylene vinyl acetate (EVA), and said membranes have been used in vivo in a manner which demonstrates their therapeutic potential."); col. 5:28-34 (" . . . underlayment material of controlled pore size can be created and used to fabricate a device of optimal porosity . . . and accessibility of the releasable macromolecule to biological material at or beyond the membrane's external surface . . ."); col. 10:12-22 ("This [microporous character] preserves the ability of external fluids or gases to intercalate the porous network in a relatively unrestricted manner."); col. 13:53-65; col. 14:1-28; col. 14:66-15:67; col. 21:49-61 ("For optimal nerve regeneration, it may be necessary or appropriate to create said tube in a manner that selectively allows the transport of some nutrients

and macromolecules across said tube, while excluding larger macromolecules."); col. 21:66-22:1; col. 31:57-32:7; col. 32:16-22.

Palmaz '665: Fig. 1A, 1B, 2A, and 2B; col. 9: 7-15 ("Further, in theory, the amount of preserved endothelium should be large because in the expanded configuration of graft 70, potentially 80% of the endothelium is exposed through openings 82 of graft 70. If (sic) is further believed that intact patches of endothelium between the elongate member 75, 76, 78, 79 of graft 70 may result in a rapid, multicentric endothelialization pattern as shown by experimental studies.").

Palmaz '762: Col. 10: 17-25 ("Further, in theory, the amount of preserved endothelium should be large because in the expanded configuration of graft 70, potentially 80% of the endothelium is exposed through the openings or expanded slots 82 of graft 70. It is further believed that intact patches of endothelium within expanded slots 82 of graft 70 may result in a rapid, multicentric endothelialization pattern as shown by experimental studies."); col. 10: 44-48 ("Further, it may be desirable to have a plurality of openings 94 formed in coating 90, as shown in FIG. 5, whereby the fluid contained in body passageway 80 can be in direct contact with the dilated, or expanded, body passageway area."); Figure 5.

Palmaz '337: Col. 9: 15-23 ("Further, in theory, the amount of preserved endothelium should be large because in the expanded configuration of graft 70, potentially 80% of the endothelium is exposed through the openings or expanded slots 82 of graft 70. It is further believed that intact patches of endothelium within expanded slots 82 of graft 70 may result in a rapid, multicentric endothelialization pattern as shown by experimental studies."); col. 9: 42-46 ("Further, it may be desirable to have a plurality of openings 94 formed in coating 90, as shown in FIG. 5, whereby the fluid contained in body passageway 80 can be in direct contact with the dilated, or expanded, body passageway area."); Figure 5.

Aebischer III: p.474 ("To test this hypothesis, we used a semi-permeable acrylic copolymer tube, a biomaterial that has displayed good *in vivo* biocompatibility, as a peripheral nerve guidance channel. The molecular weight cut-off of the material used was expected to 1) allow nutrient exchange across its wall; 2) retain within the lumen trophic or growth factors secreted by the severed nerve; and 3) prevent fibroblastic infiltration into the regenerating cable.").

Aebischer IV: p.599 ("Using the mouse sciatic nerve model, it was observed that permselective channels with a molecular weight cut-off of 50 000 daltons allowed the regeneration of nerves which more closely resembled the normal sciatic nerve . . . than channels impermeable (silicone, polyethylene) or freely permeable The latter observation suggests that controlled exchange across the guidance channel wall favors the formation of a regenerating environment leading to enhanced regeneration."); p. 600 ("These tubes feature a partially fenestrated outer skin and a permselective inner skin connected by an open trabecular network which provides the channel's structural support (Fig. 1). The permselective inner skin has a nominal molecular weight cut-off of 50 000 daltons.").

Claim 10 [10A]: The method of claim 8, wherein molecules produced by the damaged tissue are substantially restricted adjacent to the damaged tissue.

Where Found in the Prior References:

Schwartz '823: Abstract; col. 2:29-40; col. 2:49-53; col. 3:58-61 ("The improvement of the present invention includes applying to the above-mentioned type of stent a flexible or elastomeric polymeric film which extends between the metal elements."); col. 3:64-4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof."); col. 6:17-20; col. 7:25-8:11.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); Fig. 3; col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-33; col. 5:34-6:29; col. 6:37-41; col. 6:41-45 ("Modifications of the polymer coating include a ring that encompasses the proximal portion of the stent, single or multiple strips that cover a portion of the stent, or a polymer coating with perforations."); col. 8:23-25 ("Ethylene vinyl acetate copolymer (EVA) (Catalog #34,691-8) was obtained from Aldrich Chemical Company, Inc. (Milwaukee, Wis.); col. 10:24-33; col. 12:1-6; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow Controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Col. 1:7-10 ("This invention relates generally to expandable intraliminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable

of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 1:64-2:2 ("The polymer material can be a thermoplastic or an elastomer, for example, so that the film can stretch or deform radially when the stent structural member is expanded. The film of polymer material can be formed as a solid sheet, or can incorporate holes of various sizes and shapes to promote rapid endothelialization."); col. 4:15-24; col. 4:25-46; col. 4:47-5:3; col. 5:4-9; col. 5:49- 6:25 ("The polymeric material is preferably selected from thermoplastic and elastomeric polymers. . . . In another currently preferred embodiment, the polymeric material can be ethylene vinyl acetate (EVA) . . ."); col. 6:26-65; col. 7:23-42; col. 7:63-65; col. 8:12-57; col. 9:5-12; col. 10:12-30.

Wolff '208: Col. 2:7-16 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:28-30 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 6:59-62 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously. The polymer may be biostable or bioabsorbable. If biostable, the drug would diffuse out of the polymer."); col. 6:64-67; col. 7:59-61; col. 9:23-33 ("That layer may be a simple barrier which limits diffusion of drugs in the polymer. In that event, the smaller molecules could elute out immediately, while larger compounds would not elute until later when the layer has biodegraded."); col. 12:37-40 ("8. The device of claim 1 also comprising a barrier coating of polymeric material on the drug-containing filament to limit the rate of drug elution.").

Berg '354: Page 2:43-54 ("Viewed from a further aspect the invention provides the use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug-eluting surface coating."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:29-31 ("Also, stents made with biostable or bioabsorbable polymers such as poly(ethylene terephthalate), polyacetal, poly(lactic acid), poly(ethylene oxide)/poly(butylene terephthalate) copolymer could be used in the present invention. "); Table 1; p. 4:5-24; p. 6:6-11; p. 6:15; p. 6:24-35; p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Abstract ("A stent made of biodegradable material includes a drug that is released at a rate controlled by the rate of degradation of the biodegradable material."); col. 2:16-

17; col. 4:1-5 ("In one embodiment, the main body includes a film that is preferable combined with the plurality of fibers disposed around the main body. The film combined with the plurality of fibers defines the outer surface of the main body."); col. 4:15-16 ("Preferable, the main body of the stent includes a film covering the inner surface."); col. 4:19-22.

Ding '536: Abstract ("The coating includes a relatively thin layer of biostable elastomeric material containing an amount of biologically active material, particularly heparin, dispersed in the coating in combination with a non-thrombogenic surface."); col. 1:24-29 ("The present invention relates generally to providing biostable elastomeric coatings on the surfaces of implants which incorporate biologically active species having controlled release characteristics in the coating particularly to providing a non-thrombogenic surface during and after timed release of the biologically active species."); col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 5:10-56 ("Polymers generally suitable for the undercoats or underlayers include silicones (e.g., polysiloxanes and substituted polysiloxanes), polyurethanes, thermoplastic elastomers in general, ethylene vinyl acetate copolymers, polyolefin elastomers, polyamide elastomers, and EPDM rubbers. The above-referenced materials are considered hydrophobic with respect to the contemplated environment of the invention."); col. 12:62-13:2; col. 13:13-26; col. 13:37-40; col. 14:5-17; col. 14:22-34.

Dinh '227: Col. 2:51-54 ("To accomplish this while not affecting the strength of the overall fibrin stent structure, a first layer is applied to a stent body, the first layer incorporating a polymer and the therapeutic substance."); col. 2:62-66 ("The inclusion of a polymer in intimate contact with a drug on the underlying stent structure allows the drug to be retained on the stent in a resilient matrix during expansion of the stent and also slows the administration of drug following implantation."); col. 3:10-14; col. 3:25-38; col. 5:3-7; col. 5:44-55; col. 5:56-57; col. 6:13-19 ("In U.S. Pat. No. 4,548,736 issued to Muller et al., a dense fibrin composition is disclosed which can be a bioabsorbable matrix for delivery of drugs to a patent. Such a fibrin composition can also be used in the present invention by incorporating a drug or other therapeutic substance useful in diagnosis or treatment of body lumens to the fibrin provided on the stent."); 6:50-56 ("Alternatively . . . a dense fibrin composition suitable for drug delivery can be made without the use of microcapsules by adding the drug directly to the fibrin followed by compression of the fibrin into a sufficiently dense matrix that a desired elution rate for the drug is achieved."); col. 6:62-67; col. 7:10-13; col. 7:56-64 ("In another embodiment of the invention, the coating of polymer and drug on the stent is achieved by forming a first fibrin layer on the stent body which incorporates the therapeutic substance and then applying a second layer of fibrin."); col. 8:52-60 ("Fig. 2 shows an alternative stent in which a fibrin film has been affixed to the underlying metallic framework by affixing it to the stent . . ."); col. 8:64-9:3; col. 12:24-28; col. 12:38-50.

Domb '055: Abstract ("Devices are provided having a polymer coating incorporating compounds inhibiting inflammation and infection, along with subsequent tissue growth onto and around the device. . . . Preferred polymeric coating are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or

ethylene vinyl acetate."); col. 1:12-15 ("This invention relates to invasive medical devices for delayed/sustained release of pharmaceutical compositions from a polymer that is coated or incorporated into the devices."); col. 3:54-57 ("In the preferred embodiments, these have utilized bioerodible polymers as the matrix for the drug to be released, usually as a function of diffusion and erosion of the polymer."); col. 4:22-36; col. 5:24-37; col. 5:41-45; col. 5:48-6:1; col. 6:24-26 ("Examples of suitable polymers include ethylene vinyl acetate, polyurethane, silicones, hydrogels, polyurethane, and polyvinyl chloride."); col. 7:10-20; col. 7:40-52; col. 9:15-30; col. 9:55-10:2; col. 10:21-52; col. 10:60-11:11; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 11:36-38 ("The medical device of claim 1, wherein the polymer is selected from the group consisting of polyurethane, ethylene vinyl acetate, silicones, hydrogels, and polyvinyl chloride."); col. 11:39-44; col. 12:11-22; col. 12:23-25; col. 12:26-31; col. 12:32-42.

Fox '096: Abstract ("A method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers, and antimicrobial agents . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 2:48-65; col. 3:55-67 ("The polymeric coating agent component of the coating vehicle of the present invention is selected from the group consisting of biomedical polyurethanes, biomedical silicones, biodegradable polymers and combinations thereof."); col. 19:11-16; col. 31:62-64.

Hunter '981: Col. 1:12-17; col. 3:42-45 ("Within one aspect of the present invention, compositions are provided (anti-angiogenic compositions) comprising (a) an anti-angiogenic factor and (b) a polymeric carrier."); col. 3:53-61; col. 12:23-25 ("As noted above, the present invention provides compositions comprising an anti-angiogenic factor, and a polymeric carrier."); col. 16:31-56; col. 17:63-18:7 ("[T]he anti-angiogenic compositions of the present invention may be formed as a film. . . . Such films are preferably flexible with a good tensile strength . . . and has controlled permeability."); col. 22:3-7; col. 22:54-58; col. 47:58-49:7; col. 52:4-8; col. 69:19-62; col. 84:62-86:24; 86:56-59; col. 87:11-22; col. 88:19-26.

Kowligi '782: Abstract ("The elastomeric coating is made of polyurethane or another biocompatible non-porous elastomers and precludes tissue ingrowth into the outer cylindrical wall, minimizes suture hold bleeding, and increases suture retention strength, while reducing the incidence of serous weepage."); col. 1:18-26; col. 2:15-20; col. 2:38-47; col. 2:53-59; col. 3:27-37; Fig. 1; Fig. 2; Fig. 3; col. 2:60-67 ("PTFE tube 32 includes an inner cylindrical wall and an

opposing outer cylindrical wall. As shown in Fig. 2, outer cylindrical wall 36 is coated entirely around its circumference by a uniformly thick coating of a biocompatible elastomer."); col. 3:27-38; col. 4:16-27 ("In regard to elastomeric coating 38 shown in Fig. 2, such elastomeric coating is selected to be a biocompatible elastomers and may be selected from the group consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 4:37-39 ("The elastomeric coating should also be sufficiently non-porous to preclude serous weepage and inhibit tissue ingrowth therethrough."); col. 5:4-7; col. 7:49-8:9; col. 8:38-44; col. 9:65-10:6; col. 10:18-24; col. 10:33-42; col. 10:43-50; col. 10:51-59; col. 10:60-67.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 2:16-35; col. 2:40-50; col. 3:8-12; col. 3:29-32; col. 3:33-49; col. 3:55-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); col. 7:29-32; col. 7:38-41; col. 10:57-64; col. 11:49-51; col. 11:65-12:13; col. 12:43-64; col. 13:13-19.

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p. 3:10-31 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); p. 4:2-12; p. 6:21-28 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); claim 1:1-14; claim 8:1-5; claim 10:1-3; claim 11:1-13; claim 22; claim 23:1-14; claim 19:4-31.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8.

Myler '563: Col. 2:10-13; col. 3:13-15; col. 3:52-54; col. 4:30-43 ("In a preferred embodiment, the interior and exterior walls of stent 10 are enclosed in a thin polymeric envelope. . . . Suitable envelope materials include elastic materials such as latex and others that can be readily selected by one of skill in the art."); col. 5:1-16; col. 5:39-41 ("For the above reasons, even the expanded pores for drug delivery should be small enough to maximize or prevent cell penetration, but large enough for drug delivery."); col. 12:11-13; col. 12:19-23; col. 12:28-33

("Suitable materials include elastomeric polymers or natural rubber (latex). . . . Polymeric stents can be provided with relatively fluid impenetrable walls, or porous walls such as to allow drug delivery, as will be apparent to one of skill in the art."); col. 12:63-65 ("Suitable coating materials include elastic materials such as polyethylene or PET or other materials that can be readily selected by one of skill in the art."); col. 18:51-19:9; col. 19:18-30; col. 19:31-32; col. 19:61-63; col. 20:33-49; col. 20:51-57.

Palmaz '417: Col. 6:66-68; col. 11:3-14 ("Examples of a suitable biologically compatible coating would be porous polyurethane, Teflon™ or other conventional biologically inert plastic materials."); col. 11:26-31 ("Examples of biologically compatible coatings would include coatings made of absorbable polymers such as those used to manufacture absorbable sutures. Such absorbable polymers include polyglycoides, polyacoides, and copolymers thereof.").

Tice '330: Col. 3:20-33 ("Suitable wall forming materials include polystyrene, ethylcellulose, cellulose acetate, hydroxyl propylmethylcellulose phthalate, cellulose acetate, dibutylaminohydroxypropyl ether, polyvinylbutyral, polyvinyl formal, poly(meth)acrylic acid ester, polyvinylacetal-diethylamino acetate, 2-methyl-5-vinyl pyridine methacrylate-methacrylic acid copolymer, polycarbonate, polyesters, polypropylene, vinylchloride-vinylacetate copolymer, polysaccharides, glycerol distearate, and the like. A preferred group of polymeric wall forming materials includes those which are biodegradable such as aliphatic polyesters including polylactide, polyglycolide, polycaprolactone and copolymers thereof."); col. 8:38-51.

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); col. 3:7-18; col. 3:56-63; col. 4:31-34 ("The outer membrane surface is nonporous, while porous inner membrane surface allows for the diffusion therethrough of active factor 26."); col. 5:18-28 ("In a preferred embodiment of the invention, the outer surface of the membrane is impermeable to solutes of any size, while the inner membrane surface contains pores [that] enable the active factors to diffuse out of the membrane and into the lumen of the channel."); col. 6:17-22 ("The layering procedure allows deposition of an impermeable coat on the outer surface of the device, insuring that the active factors incorporated into the membrane walls will be inhibited from diffusing through the external surface, and will diffuse only through the inner membrane surface into the lumen of the channel."); 6:54-61; col. 9:18-10:3.

Folkman '560: col. 2:43-68 ("A biocompatible plastically deformable polymer matrix . . . substantially impermeable to a macromolecule"); col. 3:18-23 ("The polymer matrixes, which are suitably used in the present invention, are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:36-51 ("Typical polymeric material suitable for forming the matrix . . . include . . . alkylene-vinyl acetate copolymers . . . crosslinked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:52-4:26 ("In the presently preferred embodiment the polymeric materials useful for forming the matrix are the ethylene vinyl ester copolymers of the general formula . . ."); col. 11:56-12:20.

Cohen '496: Col. 3:26-45 ("The polymer matrices . . . are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:65-4:39 ("In a presently preferred embodiment, the polymeric materials useful for forming the matrix are the ethylenevinyl ester copolymers of the general formula . . ."); col. 9:40-10:17; col. 10:18-32.

Schiraldi '243: Col. 1:8-21 ("The extruded film drug delivery system of the present invention, which has incorporated therein the medicament to be dispensed, is so thin and flexible when wet as to be unobtrusive to the patient after it has been properly positioned and placed in the mouth."); col. 1:58-60; col. 2:30-51; col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 9:36-55; col. 10:12-18.

Valentini '029: Abstract ("Medical devices employing semipermeable materials, such as acrylic copolymers, polyurethane isocyanate, and other biocompatible semipermeable polymers, are disclosed for use as guidance channels in regenerating nerves. . . . The guidance materials are chosen such that they are capable of allowing the diffusion of nutrients and other metabolites to the regenerating nerve site while excluding fibroblasts and other scar-forming cells."); col. 2:29-57 ("It has been discovered that the repair of severed or avulsed nerves can be greatly enhanced by the use of selectively permeable polymeric materials as nerve guidance channels. . . . The devices can be formed from various polymeric materials, such as acrylic copolymers, polyvinylidene fluoride or polyurethane isocyanate Preferable, the materials allow passage therethrough of solutes having a molecular weight of about 100,000 daltons or less. . . . The nerve guidance channels of the present invention are also preferably designed to retain nerve growth factors secreted at the anastomatic site or seeded therein, as well as retain any luminal matrix material placed inside the guidance channels."); col. 2:58-3:14; col. 4:46-59; col. 5:13-32 ("The success rate and quality of peripheral nerve regeneration was dramatically enhanced through the use of a semipermeable material."); col. 5:42-6:12 ("The permselective characteristics of the inner membrane allow the exchange of nutrients, while concentrating growth factors released by the nerve and excluding scar-forming cells."); col. 6:14-24; col. 6:31-42.

Greco '135: Col. 3:48-4:1 ("These devices will consist of organic polymers and/or metallic materials including: . . . polyethylene . . . elastomeric organosilicon polymers, such as polysiloxanes, e.g. Silastic ®").

Aebischer '627: Col. 3:57-4:3 ("The polymeric insert includes pores having a molecular weight exclusion of from about 1 kD to about 1,000 kD, but preferably from about 25kD to about 100 kD."); col. 4:11-27 ("The terms 'semipermeable' is used herein to describe biocompatible membranes that allow the diffusion therethrough of molecules having a relatively low molecular weight, while excluding the passage of those having a relatively high molecular weight. . . . The semipermeable membrane can be made of various polymeric compositions such as polyvinylchloride, polyacrylonitrile, polyvinylidene fluoride, polystyrene, polymethylmethacrylate, polysulfone, and acrylic copolymers."); col. 7:57-8:14 ("In this embodiment, a semi-permeable membrane functions as a protective cell culture device for the neurotransmitter-secreting cells. The pores of the membrane should be large enough to enable the exchange of metabolites with body fluids, and to permit the diffusion therethrough of neurotransmitter produced by the cells therein, but are small enough to bar the passage therethrough of larger elements deleterious to the cells."); col. 13:31-48; col. 13:66-68; col. 14:1-2; col. 14:22-28; col. 14:54-56.

Wood '066: Abstract ("A controlled-release bandage containing therapeutic agents in a poly(vinyl alcohol) cryogel is disclosed. The bandage may include . . . hydrophobic particles to further insure controlled and constant release of therapeutic agents."); col. 2:56-66; col. 23:4-11.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:63-2:2; col. 2:12-15 ("The present invention on the other hand exploits a wrapping material that plastically deforms as it expands . . ."); col. 2:21-38; col. 2:59-64; col. 3:7-16; col. 3:27-33 ("The lining can to advantage be made of polymers or compounds thereof."); col. 3:51-62; col. 3:51-62; col. 5:49-54 ("The thread itself in an endoprosthesis of the type illustrated in Fig. 3 can also be wrapped in a coat of medicated and biodegradable wrapping material. . . . The prosthesis can of course alternatively be enclosed in a flexible-tubular coat."); col. 6:50-55; col. 6:59-62; col. 7:16-35; col. 8:4-8; col. 8:19-10:19.

Lambert '246: Abstract ("Thus, a polyurethane coating is applied to a prosthetic article, the coating then swelled . . . so that substantial quantities of biologically active compounds can be incorporated within the interstices of the polymer."); col. 2:15-34; col. 2:40-49; col. 2:53-65; col. 3:55-4:35 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility to as to enable the application of a stable coating onto substrate (i.e. the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected)."); col. 10:45-67; col. 11:34-59; col. 12:15-41.

Bellamkonda '029: Abstract ("A nerve guidance channel for use in regenerating severed nerve is prepared containing a tubular semi-permeable membrane having openings adapted to receive the ends of a severed nerve, and an inner lumen containing the matrix having an adhesive peptide fragment through which the nerve can regenerate."); col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to

derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 4:9-14; col. 4:21-39 ("Any suitable hydrogel may be used as the substrate for the bioartificial extracellular matrices of this invention."); col. 4:48-57; col. 5:10-14 ("Several physical properties of the hydrogel matrices of this invention are dependent on gel concentration. Increase in gel concentration may change the gel pore radius, morphology, or its permeability to different molecular weight proteins."); col. 7:13-25; col. 10:28-40 ("Permselective channels with a molecular weight cut-off of 50,000 daltons allowed regeneration of nerves in a mouse sciatic nerve model."); col. 10:41-63; col. 10:64-11:13; col. 12:13-16 ("Preferably the permselective membrane is fabricated to be impermeable to some of these substances so that they are retained in the proximity of the regenerating nerve ends."); col. 12:17-25 ("Briefly, various polymers and polymer blends can be used to manufacture the nerve guidance channel."); col. 12:42-49; col. 19:7-16; col. 23:54-24:55.

Dayton '382: Abstract ("The device comprises a stent which is formed from metal or polymers into a predetermined shape which includes a plurality of holes . . . to provide a desired bending modulus. The stent is then coated with a polymer . . . which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids, with the equilibrium being controlled by charge distribution, concentration and molecular weight of the bioactive substance in relation to the pore size of the polymeric carrier for controlled prolonged release of said bioactive substance."); col. 3:62-4:4:17 ("Among these polymers are polymers having a microporous structure, such as . . . biodegradable polylactic acid polymers, polyglycolic acid polymers . . ."); col. 4:24-33 ("A bioactive substance is preferably admixed in the polymer for elution from the microporous structure of the stent or coating on the stent after implantation. The rate of elution of the bioactive substance is controlled by selecting a pore size for microporous structure . . ."); col. 4: 42-50; col. 4:54-5:3; col. 6:64-7:7 ("The polymer should have a microporous structure with a predetermined pore size."); col. 8:19-33; col. 8:42-59; col. 8:66-9:5; col. 10:1-2.

Burt '036: p. 4:19-33 ("Similarly a wide variety of polymeric carriers may be utilized, representative examples of which include poly(ethylene-vinyl acetate) . . . and copolymers of polylactic acid and polycaprolactone."); p.10:17-25; p.14:9-27 ("As noted above, anti-angiogenic compositions of the present invention comprise an anti-angiogenic factor and a polymeric carrier. In addition to the wide array of anti-angiogenic factors and other compounds discussed above, anti-angiogenic compositions of the present invention may include a wide variety of polymeric carriers, including for example both biodegradable and non-biodegradable compositions."); p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size."); p.51:1-52:35.

Goldin '568: Col. 1:43-62 ("Release by controlled diffusion may be accomplished by means of containment of the therapeutic agent within a substrate whose small pore size and/or tortuosity of diffusion path thereof limits the diffusion of said agent through the substrate. . . . The therapeutic agent can be incorporated within the diffusion-limiting substrate Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-

vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:24-29 ("Microporous membranes for release of proteins by controlled diffusion have been fabricated from ethylene vinyl acetate (EVA), and said membranes have been used in vivo in a manner which demonstrates their therapeutic potential."); col. 5:28-34 (" . . . underlayment material of controlled pore size can be created and used to fabricate a device of optimal porosity . . . and accessibility of the releasable macromolecule to biological material at or beyond the membrane's external surface . . ."); Fig. 1A; col. 11:58-12:14; col. 13:53-65; col. 14:1-28; col. 14:66-15:67; col. 31:57-32:7 ("The device of claim 1 wherein said microporous underlayment comprises a polymer."); col. 32:16-22.

Palmaz '665: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3:47-51 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5: 30-32 ("FIGS. 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon."); Figures 5 and 6.

Palmaz '337: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3:52-56 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5: 19-21; Figures 5 and 6; col. 8: 28-32; col. 9: 24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '762: Col. 10:28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials."); col.3:65-4:2 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 9: 20-25; col. 10: 28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Zaffaroni '254: Abstract ("The wall is formed in at least a part of a microporous material..."); col. 1: 19-23 ("The wall of the device is comprised in at least a part of a microporous material..."); col. 3: 5-10; col. 3: 48-53; col. 4: 47-54 ("Wall 11 is formed of a microporous material the micropores 15 of which contain a drug release rate controlling medium, not shown, permeable to the passage of drug, as by diffusion, or by convection,, or by a concurrent operation of both, but the rate of passage of the drug through the medium in the micropores is lower than the rate of passage of drug through the solid drug carrier."); col. 5: 3-11.

Aebischer: p. 283 (disclosing impermeable polymer layer that restricts passage of treating material).

Dev: p. 273 ("We used a commercially available biomedical grade polyurethane Tecoflex is a biocompatible, flexible, and an elastic membrane-forming polymer.").

Claim 11 [11A]: The method of claim 8, wherein the at least one treating material is affixed to the layer prior to placement of the device adjacent to the damaged tissue.

Where Found in the Prior References:

Schwartz '823: Col. 2:59-65 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference."); col. 3:64-4:3; col. 7:1-4 ("In yet another aspect of the present invention, various therapeutic substances can be incorporated in or applied to the polymeric film to provide such substances to the blood or to the lumen wall."); col. 7:14-17 ("Application of the therapeutic substance to the film can include applying it on the surface of the film or incorporating it into the film as it is made."); col. 7:25-8:11.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14 ("The present invention satisfies this need by providing a separate sleeve to encompass the stent and serve as a local drug delivery device to prevent thrombosis."); col. 4:53-55 ("The present invention satisfies this need by providing a separate sleeve to encompass a stent to locally administer drugs to prevent restenosis."); col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-33; col. 6:49-59 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject. Finally, the invention provides a method of inhibiting vascular cell growth in a subject comprising inserting a stent encompassed by a sheath containing an inhibitor

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of vascular cell growth into a vessel of the subject."); col. 8:41-54; col. 10:24-33 ("In combination, a hollow tubular stent having a predetermined length and a separate sheath removably encompassing at least a portion of said hollow tubular stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug."); col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow Controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Col. 1:7-10 ("This invention relates generally to expandable intraliminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:41-56; col. 1:57-64; col. 4:23-24 ("The polymer material can be extruded as a thin film, and any processing can be done while the material is a flat sheet."); col. 5:4-9; col. 5:64-6:25; col. 7:23-25; col. 7:56-62 ("The elastic material attached over the coil of polymeric material helps keep the coil of drug loaded material snug on the stent structural member before it is expanded, and guides its linear expansion during inflation of a balloon dilatation catheter used for deployment of the stent and polymeric drug loaded material in the vasculature or other body lumen of a patient."); col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:63-2:6 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery. The prostheses may be completely biodegradable or may be bioabsorbable in whole or incorporated into the lumen wall as a result of tissue overgrowth, i.e. endothelialization. Alternatively, the prostheses may be biostable in which case the drug is diffused out from the biostable materials in which it is incorporated."); col. 2:12:-14 ("In all cases, the prostheses of the invention require the presence of an elutable drug compounded to the prosthesis itself. With conventional metal stents, the invention requires a drug-carrying coating overlying at least a portion of the metal.");

col. 6:59-62 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously. The polymer may be biostable or bioabsorbable. If biostable, the drug would diffuse out of the polymer."); col. 6:64-67.

Berg '354: Page 2:3-4 ("This invention relates to intravascular stents for treatment of injuries to blood vessels and particularly to stents having a framework onto which a therapeutic substance or drug is applied."); p. 2:43-54 ("Viewed from a further aspect the invention provides the use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug-eluting surface coating."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 6:6-11; p. 6:46-51.

Buscemi '450: Col. 5:46-48 ("The stent of the present invention further includes incorporation of a drug or drugs or other biologically active materials. The drugs are contained within the biodegradable materials of which the stent is composed."); col. 5:55-60 ("Drugs are incorporated into the biodegradable stent using techniques known in the art. The techniques include simple mixing or solubilizing with polymer solutions, dispersing into the biodegradable polymer during the extrusion of melt spinning process, or coating onto an already formed film or fiber."); col. 5:64-6:8; col. 6:31-44; col. 6:65-7:9; col. 7:21-24; col. 7:32-8:9; col. 8:27-30.

Ding '536: Col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 3:65-4:11; col. 4:19-5:13; Fig. 1; col. 7:24-35; col. 12:20-23 ("It will be appreciated that the mechanism of incorporation of the biologically active species into a thin surface coating structure applicable to a metal stent is an important aspect of the present invention.").

Dinh '227: Col. 2:51-54 ("To accomplish this while not affecting the strength of the overall fibrin stent structure, a first layer is applied to a stent body, the first layer incorporating a polymer and the therapeutic substance."); col. 2:57-61; col. 3:1-3; col. 3:14-22; col. 3:25-35; col. 4:4-5; Fig. 14; col. 6:56-61 ("In yet another method for incorporating drugs which allows the drug to elute at a controlled rate, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic drug dispersed in the solvent is applied to the structural elements of the stent and then the solvent is evaporated."); col. 7:56-64; col. 7:67-8:19; col. 9:18-24; col. 9:53-63; col. 9:64-10:28 ("Preferably, heparin is incorporated into the stent prior to implantation in an amount effective to prevent or limit thrombosis."); col. 11:25-30; col. 11:60-62.

Domb '055: Col. 5:24-27 ("Devices are provided having a polymer coating incorporating compounds inhibiting inflammation and infection, along with subsequent tissue growth onto and around the device."); col. 5:35-38; col. 5:46-48; col. 5:60-6:1; col. 6:3-7; col. 6:33-40 ("The biologically active agent to be released is incorporated at the time of casting or melting, or subsequently, by absorption, with both the coatings and the devices, in whole or in part."); col.

7:10-20; col. 7:40-52; col. 9:15-30; col. 9:55-10:2; col. 10:21-52; col. 10:60-11:11; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 2:48-65; col. 15:20-33; col. 16:16-23 ("The catheter was dipped in the coating vehicle while the vehicle was being continuously agitated to insure a uniform suspension. The coated catheter was the dried. A tightly adherent coating on the catheter was thus provided."); col. 22:31-37; col. 30:49-53.

Hunter '981: Col. 4:62-67; col. 17:7-26; col. 22:40-64 ("Stents may be coated with anti-angiogenic compositions or anti-angiogenic factors of the present invention in a variety of manners, including for example: (a) by directly affixing to the stent an anti-angiogenic composition (e.g., by either spraying the stent with a polymer/drug film, or by dipping the stent into a polymer/drug solution) . . . (d) by inserting the stent into a sleeve of mesh which is comprised of or coated with an anti-angiogenic composition . . ."); col. 23:6-13 ("[M]ethods are provide for expanding the lumen of a body passageway, comprising inserting a stent into the passageway, the stent having a generally tubular structure, the surface of the structure being coated with an anti-angiogenic composition . . . such that the passageway is expanded."); col. 44:60-45:31; col. 47:58-49:7; col. 48:7-49:7; col. 69:19-62 ("In this study, strecker stents were coated with an EVA polymer containing paclitaxel at concentration of 33%, 10%, and 2.5% and were tested for their ability to inhibit angiogenesis on the CAM."); col. 84:62-86:24; 86:56-59; col. 87:11-22; col. 88:19-26.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 5:56-6:34; col. 10:57-64; col. 11:49-51; col. 11:65-12:13; col. 12:43-64; col. 13:13-19.

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological

conditions, the biologically active compound is slowly released by the treated polymer."); p. 10:17-11:15; claim 1:1-14; claim 8:1-5; claim 10:1-3; claim 11:1-13; claim 22; claim 23:1-14; claim 19:4-31.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8 p. 3:11-13.

Myler '563: Col. 4:57-59 ("The envelope can act as a reservoir and be filled with a medication prior to implantation at the desired treatment location.").

Palmaz '417: Col. 11:3-34.

Aebischer '486: Abstract ("The devices are formed from a porous, tubular membrane containing active factor incorporated within the membrane and having openings adapted to receive the ends of the severed nerve."); col. 2:60-63; col. 4:29-31; col. 6:27-8:30; col. 9:18-10:3.

Folkman '560: Col. 5:1-19; col. 6:61-7:50; col. 11:56-12:43.

Cohen '496: Col. 2:30-36; col. 2:46-66 ("In general, the invention features an improved method of making such a body, in which a biologically active material and the polymer below the glass transition temperature of the polymer and compressing the mixture above the glass transition point of the polymer."); col. 4:66-5:16; col. 6:59-64; col. 7:57-8:12; col. 9:40-10:17.

Schiraldi '243: Col. 2:44-51 ("Various therapeutic agents are incorporated into the film during manufacture . . .").

Aebischer '627: Col. 5:52-6:33; col. 7:3-28.

Wood '066: Col. 2:55-66 ("Bandages comprising cryogel and therapeutic agents are used to provide a protective covering and to provide a controlled and uniform administration of therapeutic agents to sites of trauma . . ."); col. 4:5-9 ("After this sterilization, it was convenient to add whatever other sterile solid or liquid components (antibiotics, growth factors, therapeutic agents, etc. discussed in a following section) needed in the final bandages device of this invention.").

Strecker '746: Col. 3:5-7 ("Another sensible advanced version is characterized in that medications in the lining are dissolved in the wrapping material or included in the form of beads."); col. 3:41-62; col. 4:1-4; col. 4:23-28.

Lambert '246: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 2:15-34; col. 2:40-49; col. 2:53-65; col. 10:45-12:53.

Bellamkonda '029: Col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention."); col. 5:32-48; col. 11:41-50.

Dayton '382: Abstract; col. 4:4-17; col. 7:44-66.

Burt '036: p.21:25-22:6; p.45:32-46:27; p.51:1-52:34.

Goldin '568: Col. 4:25-57; col. 17:40-54 ("[S]ynthetic polymers . . . may be derivatized to attach functional groups which may react under appropriate circumstances to form covalent bonds with the macromolecules one wishes to bind and release in a controlled manner.").

Aebischer: p. 283 (disclosing incorporation of treating material into polymer prior to implantation into the body).

Dev: p. 273-76 (describing loading polymer with drug prior to implantation into animals).

Claim 13 [13A]: The method of claim 8, whereby the layer is capable of being affixed to a fixation device prior to implantation of the device adjacent to the damaged tissue.

Where Found in the Prior References:

Schwartz '823: Abstract ("A radially expandable stent for implantation within a body lumen having a generally cylindrical body with open proximal and distal ends, the cylindrical body comprising a plurality of metal elements joined to allow flexing of the cylindrical body along the longitudinal axis of the body whereby the stent can conform to a curved body lumen and a polymeric film extending between the metal elements of the stent. The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen."); col. 2:49-53 ("The polymeric film is flexible and preferably an elastic or stretchable film that is capable of conforming to the movement of the metallic stent elements when expanded into contact with a body lumen."); col. 3:58-61 ("The improvement of the present invention includes applying to the above-mentioned type of stent a flexible or elastomeric polymeric film which extends between the metal elements."); col. 4:20-24 ("The term 'film' or 'flexible film' herein therefore means that, as applied to the metal stent elements in a thin cross section, the film is capable of flexing or stretching to preserve the radial expandability and axial flexibility of the implanted stent."); col. 5:59-6:2; col. 6:17-38; col. 6:40-43; col. 6:59-62 ("The flexible film can be applied as a sheath to

the metal stent elements after which the stent can be compressed, attached to a catheter, and delivered through a body lumen to a desired location."); col. 8:27-32.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); Fig. 3; col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-33; col. 6:37-45 ("The invention also provides a kit comprising the sheath and a stent. Also disclosed is a device comprising a stent encompassed by the sheath. The initial prototype is a sleeve of polymer, either degradable or non-degradable, that covers the entire stent (Fig. 3). Modifications of the polymer coating include a ring that encompasses the proximal portion of the stent, single or multiple strips that cover a portion of the stent, or a polymer coating with perforations."); col. 6:49-59 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject. Finally, the invention provides a method of inhibiting vascular cell growth in a subject comprising inserting a stent encompassed by a sheath containing an inhibitor of vascular cell growth into a vessel of the subject."); col. 8:58-60; col. 10:24-33 ("In combination, a hollow tubular stent having a predetermined length and a separate sheath removably encompassing at least a portion of said hollow tubular stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug."); col. 12:9-12; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow Controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Col. 1:7-10 ("This invention relates generally to expandable intraliminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location

being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 2:3-55; col. 3:30-32; col. 3:36-39 ("Fig. 9 is a plan view of a sheet of polymeric material in another alternative embodiment including elastic strips for securing the polymeric material wrapped around a stent structural member;"); col. 3:40-41; col. 3:51-54 ("Fig. 14 is a plan view of a sheet of polymeric material in a further alternative embodiment including attachment tabs for securing the polymeric material to a stent structural member;"); Fig. 15; col. 3:55-57 ("Fig. 15 is an elevational view of a drug loaded stent wrapped with the sheet of polymeric material of Fig. 14 and mounted on a balloon dilation catheter for delivery."); Fig. 16; col. 3:58-60 ("Fig. 16 is an enlarged partial sectional view of the drug loaded stent of Fig. 15 showing the sheet of polymeric material wrapped around a slotted tube stent structural member."); col. 4:15-24; col. 4:25-46 ("The planar sheet of polymeric material is preferably adapted to uncoil and expand to match the expansion of the stent structural member. . . . The stent can be mounted on a balloon dilatation catheter, for deployment of the stent in the vasculature of the patient."); col. 4:47-5:3; col. 5:4-9; col. 5:15-17; col. 5:18-25; col. 5:25-31; col. 5:36-48 ("A representative stent structural member with which a sheet of polymeric material can be combined according to the principles of the invention is illustrated in Fig. 8."); col. 6:26-65 ("In another currently preferred embodiment illustrated in Figs. 9-13, the stent that can be drug loaded comprises a stent metal structural member, such as the stent structural member illustrated for example in Fig. 8, and a planar sheet or film of polymeric material, preferably including a plurality of apertures, as will be further explained below."); col. 7:42-53; col. 7:56-62 ("The elastic material attached over the coil of polymeric material helps keep the coil of drug loaded material snug on the stent structural member before it is expanded, and guides its linear expansion during inflation of a balloon dilatation catheter used for deployment of the stent and polymeric drug loaded material in the vasculature or other body lumen of a patient."); col. 8:1-57; col. 9:12-18; col. 9:19-22; col. 10:12-30.

Wolff '208: Col. 2:12-16 ("In all cases, the prostheses of the invention require the presence of an elutable drug compounded to the prosthesis itself. With conventional metal stents, the invention requires a drug-carrying coating overlying at least a portion of the metal."); col. 6:56-58 ("The stent shown in Figs. 2 and 4 is a metallic malleable design which may be forced against a lumen wall by a balloon catheter which fixes it into position."); col. 6:59-62 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously."); col. 9:39-42 ("The device is fixed into place either by radial expansion in devices such as shown in Fig. 1 or are deformed by a balloon catheter in the case of devices in accordance with Fig. 2."); col. 9:60-10:3 ("In yet another embodiment of the invention, a purely polymeric prosthesis such as that having the configuration shown in Fig. 1 can be combined with an expandable metal stent to provide additional support for the prosthesis. . . . By including a metal stent within the lumen of the polymeric prosthesis, the polymeric

prosthesis is effectively held against the wall of the body lumen by the strength of the metal stent."); col. 10:3-45 ("The stents are arranged on the distal end of the catheter such that the catheter can provide remote, transluminal deployment of the stents, with the metal stent inside the polymeric stent, from an entry point into a selected portion of the body lumen to be treated and also remote actuation of an expansion mechanism from the proximal end of the catheter. The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen."); col. 10:46-59; col. 10:59-11:20; col. 11:50-53.

Berg '354: Page 2:3-4 ("This invention relates to intravascular stents for treatment of injuries to blood vessels and particularly to stents having a framework onto which a therapeutic substance or drug is applied."); p. 2:43-53 ("Viewed from a further aspect the invention provides the use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug-eluting surface coating."); p.2:55-3:7; p. 3:31-34; p.3:54-55 ("The solution is applied to the stent and the solvent is allowed to evaporate, thereby leaving on the stent surface a coating of the polymer and the therapeutic substance."); p. 6:6-11; p. 6:17-19; p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Ding '536: Col. 1:24-32 ("The present invention relates generally to providing biostable elastomeric coatings on the surfaces of implants which incorporate biologically active species having controlled release characteristics in the coating particularly to provide a non-thrombogenic surface during and after timed release of the biologically active species. The invention is particularly described in terms of coating on therapeutic expandable stent prostheses for implantation in body humans, e.g., vascular implantation."); col. 3:19-27 ("Accordingly, it is primary object of the present invention to provide a coating and process for coating a stent to be used as a deployed stent prostheses, the coating being capable of effective controlled long-term delivery of biologically active materials."); col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 12:20-23 ("It will be appreciated that the mechanism of incorporation of the biologically active species into a thin surface coating structure applicable to a metal stent is an important aspect of the present invention."); col 13:13-26 ("A medical device having at least a portion which is implantable into the body of a patient, wherein at least a part of the device portion is metallic and at least part of the metallic device portion is covered with a coating for release of at least one biologically active material . . .").

Dinh '227: Col. 3:41-46 ("Fig. 1 is an elevational view of a balloon catheter with a metallic stent including a fibrin coating according to the present invention. . . ."); Fig. 1; Fig. 2; col. 3:64-65; Fig. 10; col. 5:3-7; col. 6:56-67 ("The inclusion of a polymer in intimate contact

with a drug on the underlying stent structure allows the drug to be retained on the stent in a resilient matrix during expansion of the stent and also slows the administration of drug following implantation."); col. 7:10-21; col. 7:56-64 ("In another embodiment of the invention, the coating of polymer and drug on the stent is achieved by forming a first fibrin layer on the stent body which incorporates the therapeutic substance and then applying a second layer of fibrin."); col. 8:26-43 ("The stent can also have underlying polymeric or metallic structural elements onto which the fibrin is applied or the stent can be a composite of fibrin intermixed with a polymer."); col. 8:49-60; col. 9:49-50 ("The resulting fibrin stent includes the stent embedded in a very thin elastic film of fibrin."); col. 9:59-63; col. 10:29-31 ("The metal stent portion mentioned above may be eliminated to make a fibrin tube which can be placed on a balloon catheter and expanded into place in a body lumen."); col. 11:60-62 ("It will be readily appreciated that a fibrin stent with an attached metallic framework can be readily provided by this molding method."); col. 12:24-28.

Domb '055: Abstract ("Preferred polymeric coatings are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); col. 1:12-15 ("This invention relates to invasive medical devices for delayed/sustained release of pharmaceutical compositions from a polymer that is coated or incorporated into the devices."); col. 4:33-36; col. 5:24-27 ("Devices are provided having a polymer coating incorporating compounds inhibiting inflammation and infection, along with subsequent tissue growth onto and around the device."); col. 5:35-38; col. 5:46-48; col. 5:60-6:1; col. 6:3-7; col. 7:10-20; col. 7:40-52; col. 9:15-30; col. 9:55-10:2; col. 10:21-52; col. 10:60-11:11; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Col. 1:33-36 ("In addition, antimicrobial compositions useful as coatings for medical devices or for forming the device itself are disclosed . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 2:48-65; Col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages."); col. 16:16-23 ("The catheter was dipped in the coating vehicle while the vehicle was being continuously agitated to insure a uniform

suspension. The coated catheter was the dried. A tightly adherent coating on the catheter was thus provided."); col. 19:11-16; col. 22:31-37; col. 30:49-53; col. 36:65-37:7.

Hunter '981: Col. 1:12-17 ("The present invention relates generally to compositions and methods for treating cancer and other angiogenic-dependent diseases, and more specifically, to compositions comprising anti-angiogenic factors and polymeric carriers, stents which have been coated with such compositions, as well as method for utilizing these stents and compositions."); col. 4:20-23; col. 4:38-41; col. 5:14-16; col. 5:17-22; col. 5:28-32; col. 22:3-6 ("As noted above, the present invention also provides stents, comprising a generally tubular structure . . . the surface of which is coated with a composition as described above."); col. 22:23-39 ("Representative examples of stents include those described in . . ."); col. 22:40-64 ("Stents may be coated with anti-angiogenic compositions or anti-angiogenic factors of the present invention in a variety of manners, including for example: (a) by directly affixing to the stent an anti-angiogenic composition (e.g., by either spraying the stent with a polymer/drug film, or by dipping the stent into a polymer/drug solution) . . . (d) by inserting the stent into a sleeve of mesh which is comprised of or coated with an anti-angiogenic composition . . ."); col. 23:6-12; col. 23:46-51; col. 24:45-51; col. 24:66-25:5; col. 25:24-29; col. 25:48-54; col. 26:24-29; col. 69:22-26 ("In this study, strecker stents were coated with an EVA polymer containing paclitaxel at concentration of 33%, 10%, and 2.5% and were tested for their ability to inhibit angiogenesis on the CAM."); 86:56-59; col. 87:11-22; col. 88:19-26.

Kowligi '782: Abstract ("A non-porous coated PTFE graft includes a PTFE tube having a conventional porous inner cylindrical wall and a non-porous elastomeric coating applied over at least a portion of the outer cylindrical wall of the PTFE tube to render such portion of the outer cylindrical wall non-porous."); col. 2:38-47; col. 2:53-67; col. 3:7-12; col. 3:27-37; Col. 2:60-67 ("PTFE tube 32 includes an inner cylindrical wall and an opposing outer cylindrical wall. As shown in Fig. 2, outer cylindrical wall 36 is coated entirely around its circumference by a uniformly thick coating of a biocompatible elastomer."); col. 5:4-7; col. 5:16-21.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 3:49-53; col. 5:57-61; col. 7:55-58; col. 11:52-56 ("The method in accordance with claim 1, wherein the substrate is selected from the group consisting of a metallic stent, a heart valve, a metallic prosthesis, a prosthetic joint, a pacemaker, a catheter, a balloon coating, an ocular implant and a contact lens").

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p. 10:17-21; p. 13:20-24; claim 8 ("The method according to claim 1, wherein the substrate is

selected from a metallic stent, a heart valve, a metallic prosthesis, a prosthetic joint, a pacemaker, a catheter, a balloon coating, an ocular implant or a contact lens").

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8; p. 2:29-30; p. 3:11-13.

Myler '563: Col. 2:13-15; col. 4:30-43 ("In a preferred embodiment, the interior and exterior walls of stent 10 are enclosed in a thin polymeric envelop."); col. 4:44-52 ("The envelope may be produced, for example, by inserting the stent into a preformed tubular envelope having one open end and sealing the envelope closed, or other techniques within the skill in the art."); col. 5:1-16; col. 5:50-54; col. 12:63-13:1; col. 13:5-14.

Palmaz '417: Col. 11:3-8 ("With reference now to Figs. 5 and 6, prostheses, or grafts of the type previously described in connection with Figs. 1A and 1B are shown, and the tubular members of grafts, or prostheses, have a biologically inert or biologically compatible coating placed upon wall surfaces of tubular shaped members."); col. 13:51-53 ("The method of claim 1, wherein at least one prosthesis is provided with a biologically compatible coating on the outer surface of the prosthesis.").

Wood '066: Col. 7:51-65 ("The PVA cryogel bandage may be supported by a woven or non-woven fabric of film support."); col. 23:15-23.

Strecker '746: Abstract; col. 1:63-2:2; col. 2:12-15 ("The present invention on the other hand exploits a wrapping material that plastically deforms as it expands and accordingly exerts no restoration force on the stent, ensuring persistent expansion."); col. 2:21-32 ("This embodiment has a wrinkled lining around the as yet unexpanded stent."); col. 2:33-38; col. 2:47-53; col. 2:59-64; col. 2:65-3:4 ("[T]he lining can be a flexible tubular membrane or sleeve wrapped around the prosthesis and secured."); col. 6:30-64; col. 7:16-35; col. 8:4-9; col. 8:19-10:19; Figs. 7 & 8.

Lambert '246: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 2:15-34; col. 2:53-65; col. 3:50-54; col. 10:51-54; col. 11:41-44; col. 12:23-26.

Dayton '382: Col. 4:4-10; col. 5:50-60; col. 8:64-65.

Burt '036: p.21:25-22:6 ("Stents may be coated with anti-angiogenic compositions or anti-angiogenic factors of the present invention using a variety of methods . . .").

Palmaz '665: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3: 55-65 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter..."); col.3:47-51 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on

its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway.").

Palmaz '762: Col.3:65-4:2 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 10: 28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '337: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3: 52-56 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5: 19-21; Figures 5 and 6; col. 9: 24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Dev: p.273-74 (disclosing mounting stent on balloon catheter for delivery).

Claim 15 [15A]: A method of treating tissues in human or veterinary medicine comprising the steps of:

Where Found in the Prior References

Peterson '166: Abstract ("The composition of the system is particularly effective for delivering medication systemically to a host animal over a prolonged period of time after being surgically implanted or injected subcutaneously."); col. 2:3-5 ("The delivery system is usually implanted subcutaneously by injection or incision in an animal, including the human body."); col. 2:24-27 ("The time-release chemical delivery systems of this invention are intended for implantation, either surgically or by injection in animals, including humans."); col. 11:23-24 ("A time release chemical delivery system for implantation in animal host comprising . . .").

Schwartz '823: Abstract ("The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen. The stent is especially useful for repairing an injury to blood vessels caused during angioplasty procedures."); col. 2:16-24 ("It is therefore an object of the present invention to provide a stent having longitudinal flexibility which allows it to conform to curves and variations in body lumens. . . . It is also an object of the present invention to provide

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a stent capable of delivering therapeutic agents to a blood vessel."); col. 2:29-37 ("In a radially expandable stent for implantation within a body lumen, the stent having a generally cylindrical body with open proximal and distal ends, the cylindrical body comprising a plurality of metal elements joined to permit flexing of the cylindrical body along its longitudinal axis to permit the stent to conform to a curved body lumen, the improvement of the present invention comprises a polymeric film extending between the metal elements."); col. 2:40-44; col. 2: 49-53; col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:48-54; col. 3:58-col. 4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof."); col. 6:17-38; col. 8:8-9 ("The stent of claim 1 wherein the film comprises a therapeutic substance.").

Scott '928: Fig. 3; Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14 ("The present invention satisfies this need by providing a separate sleeve to encompass the stent and serve as a local drug delivery device to prevent thrombosis."); col. 4:53-55 ("The present invention satisfies this need by providing a separate sleeve to encompass a stent to locally administer drugs to prevent restenosis."); col. 4:58-68 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 5:26-29; col. 6:49-55 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject."); col. 8:23-54; col. 9:12-16 ("In addition, polymer-drug films which prevent thrombosis in the baboon and pig AV shunt system can be studied following stent-film placement in carotid, superficial femoral and coronary arteries following balloon injury of those vessels."); col. 10:24-33 ("In combination, a hollow tubular stent having a predetermined length and a separate sheath removably encompassing at least a portion of said hollow tubular stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted,

comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug."); col. 10:45-47 ("A method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath of claim 2 into a vessel of the subject."); col. 10:55-57 ("8. A method of promoting vascular cell growth in a subject comprising inserting a stent encompassed by the sheath of claim 6 into a vessel of a subject."); col. 11:1-3 ("11. A method of inhibiting vascular cell growth in a subject comprising inserting a stent encompassed by the sheath of claim 9 into a vessel of the subject."); col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:12-20 ("Stents are typically implanted within a vessel in a contracted state and expanded when in place in the vessel in order to maintain patency of the vessel to allow fluid flow through the vessel. Ideally, the implantation of such stents is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:42-50; col. 1:50-56 ("The stent can be used in coronary arteries or any other part of the vasculature or other body lumen where mechanical opening force is necessary or desirable to keep the vessel open or to maintain the stent flush against the lumen wall, and where an anti-restenosis, anti-proliferative or other types of therapeutic drug or agent is to be simultaneously positioned and diffused."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 1:64-2:2; col. 4:25-46; col. 5:4-9 ("The primary function of the sheet of polymeric material is to deliver therapeutic agents or drugs to help prevent thrombosis and/or restenosis."); col. 5:18-25; col. 5:49-6:25; col. 7:56-62 ("The elastic material attached over the coil of polymeric material helps keep the coil of drug loaded material snug on the stent structural member before it is expanded, and guides its linear expansion during inflation of a balloon dilatation catheter used for deployment of the stent and

polymeric drug loaded material in the vasculature or other body lumen of a patient."); col. 9:3-18; col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:52-62 ("The invention provides prostheses which may be inserted into a lumen of a body and fixed to the lumen wall adjacent an area needing treatment. . . . [T]he methods and devices of the invention are also suited to treatment of any body lumen, including vas deferens, ducts of the gall-bladder, prostate gland, trachea, bronchus and liver or any other lumen of the body where medication cannot be applied without a surgical procedure."); col. 2:7-16 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:25-27 ("The current invention contemplates the usage of any prosthesis which elutes drugs locally to treat a lumen in need of repair."); col. 6:36-38; col. 11:47-48; 11:50-53.

Berg '354: Page 2:3-4 ("This invention relates to intravascular stents for treatment of injuries to blood vessels and particularly to stents having a framework onto which a therapeutic substance or drug is applied."); p. 2:14-18 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen. Examples of stents which have been successfully applied over a PTCA balloon and radially expanded at the same time as the balloon expansion of an affected artery include the stents disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) which are incorporated herein by reference in their entirety."); p. 3:16-18 ("In operation, the stent made according to the present invention can deliver drugs to a body lumen by introducing the stent transluminally into a selected portion of the body lumen and radially expanding the stent into contact with the body lumen."); p. 3:29-31; p. 5:53-6:1; p. 6:6-11; p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Abstract ("A stent made of biodegradable material includes a drug that is released at a rate controlled by the rate of degradation of the biodegradable material."); col. 2:55-56 ("The present invention includes a biodegradable stent for insertion into a lumen of a vessel in a living being."); col. 3:9-11 ("The stent releases drugs into a tubular vessel having a lumen in a living being."); col. 4:46-64; col. 5:11-20; col. 6:9-28; col. 6:65-7:1; col. 7:32-3.

Ding '536: Col. 1:29-32 ("The invention is particularly in terms of coatings on therapeutic expandable stent prostheses for implantation in body lumens, e.g., vascular implantation."); col. 1:34-45; col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 5:10-56; col 13:13-26 ("A medical device having at least a portion which is implantable into the body of a patient, wherein

at least a part of the device portion is metallic and at least part of the metallic device portion is covered with a coating for release of at least one biologically active material . . .").

Dinh '227: Abstract ("An intraliminal stent comprising fibrin and an elutable drug is capable of providing a treatment of restenosis."); col. 1:11-13 ("This invention relates to a method for lessening restenosis of body lumens and to intraliminal stents having anti-thrombosis and anti-restenosis properties."); col. 1:32-35; col. 2:35-37; col. 2:62-66; col. 6:19-22 ("The drug, fibrin and stent can then be delivered to the portion of the body lumen to be treated where the drug may elute to affect the course of restenosis in surrounding luminal tissue."); col. 8:20-27 ("The term 'stent' herein means any device which when placed into contact with a site in the wall of a lumen to be treated, will also place fibrin at the lumen wall and retain it at the lumen wall. This can include especially devices delivered percutaneously to treat coronary artery occlusions and to seal dissections or aneurysms of splenic, carotid, iliac and popliteal vessels."); col. 12:24-28.

Domb '055: Abstract ("Devices are provided having a polymer coating incorporating compounds inhibiting inflammation and infection, along with subsequent tissue growth onto and around the device. Preferred embodiments include catheters, tubes and implants that abut tissue following implantation into the body . . ."); col. 1:12-18 ("This invention relates to invasive medical devices for delayed/sustained release of pharmaceutical compositions from a polymer that is coated or incorporated into the devices. The purpose of the coating or delivery system on these devices is to reduce, control or even prevent the inflammation and infection that occur with prolonged use of these devices."); col. 4:15-17; col. 4:22-32; col. 5:24-6:18; col. 6:24-26; col. 11:27-38 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Abstract; col. 1:64-2:5; col. 2:9-21; col. 2:48-65; col. 3:55-67; col. 16:16-22; col. 31:62-64; col. 36:21-31; col. 37:34-38; col. 37:66-38:9; col. 49:27-31.

Hunter '981: Col. 1:12-17 ("The present invention relates generally to compositions and methods for treating cancer and other angiogenic-dependent diseases, and more specifically, to compositions comprising anti-angiogenic factors and polymeric carriers, stents which have been coated with such compositions, as well as method for utilizing these stents and compositions."); col. 3:39-45; col. 4:14-5:36; col. 7:12-16 ("Fig. 13 is an illustration of a representative embodiment of hepatic tumor embolization. Fig. 14 is an illustration of the insertion of a representative stent coated with an anti-angiogenic composition."); Fig. 13; Fig. 14; col. 12:23-35; col. 16:31-56; col. 17:63-18:7 ("[T]he anti-angiogenic compositions of the present invention may be formed as a film. . . . Such films are preferably flexible with a good tensile strength . . . and has controlled permeability."); col. 22:3-7; col. 23:6-13 ("[M]ethods are provide for expanding the lumen of a body passageway, comprising inserting a stent into the passageway, the stent having a generally tubular structure, the surface of the structure being coated with an

anti-angiogenic composition . . . such that the passageway is expanded."); col. 23:46-51; col. 24:45-51; col. 24:66-25:5; col. 25:24-29; col. 25:48-54; col.84:63-85:4; col. 86:56-59; col. 87:11-22; col. 88:19-26; col. 87:1-2.

Kinsella '608: Col. 6:8-12 ("Each of the aforementioned applications may also be amendable to selective, localized application of sustained-release preparations of taxol (or other microtubule-stabilizing agent) which would enable high dosage local drug delivery with little systemic toxicity."); col. 11:14-24 ("Ultimately, local sustained-release delivery systems may offer the best solution to prevent restenosis post-angioplasty, enabling high local concentrations of drug delivery and essentially eliminating problems of systemic toxicity. Drug delivery systems that can be valuable include drug-impregnated polymer-coated metallic stents [and] biodegradable drug-eluting polymer stents . . . ").

Kowligi '782: Abstract ("The elastomeric coating is made of polyurethane or another biocompatible non-porous elastomers and precludes tissue ingrowth into the outer cylindrical wall, minimizes suture hold bleeding, and increases suture retention strength, while reducing the incidence of serous weepage."); col. 1:18-26 ("The present invention relates generally to prosthetic vascular grafts for implantation within the vascular system of a patient, and more particularly, to a prosthetic vascular graft made from expanded, porous polytetrafluoroethylene (PTFE) tubing that is fabricated to retain the porous inner cylindrical wall of conventional PTFE vascular grafts, but wherein the outer cylindrical wall of the PTFE tube is rendered non-porous over at least a portion of its length."); col. 4:16-27; col. 10:18-24; col. 10:33-42; col. 10:51-59.

Lambert '922: Abstract; col. 2:16-35 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); col. 2:62-67 ("In accordance with yet another embodiment of the present invention, there is provided a method for the localized delivery of biologically active compounds to a subject. This invention method comprises implanting the above-described delivery system at a site where the targeted release of said biologically active compound is desired."); col. 3:8-12; col. 3:29-32; col. 3:50-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected)."); col. 7:29-32; col. 10:54-56; col. 12:40-42; col. 13:10-12.

Lambert '308: Abstract; p. 3:10-31 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); p. 4:25-31 ("In accordance with yet another embodiment of the present invention, there is provided a method for the localized delivery of biologically active compounds to a subject. This invention method comprises implanting the above-described delivery system at a site where the targeted release of said biologically active compound is desired."); p. 6:15-20 ("Substrates suitable for use in the practice of the present invention include metallic stents, such as vascular, biliary or ureteral stents, heart valves, metallic prostheses, prosthetic joints, pacemakers, catheters, balloon coatings, ocular implants, contact lenses, and the like."); p.6:21-28 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable

coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected)."); claim 1:1-4; claim 19:1-3; claim 20; claim 27:1-5.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8.

Mitchell '711: Col. 3:24-31 ("This invention provides a method of preventing or treating hyperproliferative vascular disease in a mammal in need thereof by administering an antiproliferative effective amount of a combination of rapamycin and heparin to said mammal . . . via a vascular stent impregnated with a combination of rapamycin and heparin."); col. 7:16-20 ("Rapamycin in combination with heparin can be administered intravascularly or via a vascular stent impregnated with rapamycin in combination with heparin, during balloon catheterization to provide localized effects immediately following injury."); col. 7:56-8:7; col. 8:22-23; col. 8:39-42; col. 8:49-56.

Morris '781: Col. 3:45-50 ("This invention provides a method of preventing or treating hyperproliferative vascular disease in a mammal in need thereof by administering an antiproliferative effective amount of rapamycin to said mammal . . . via a vascular stent impregnated with rapamycin."); col. 11:41-45 ("Rapamycin, alone or in combination with mycophenolic acid can be administered intravascularly or via a vascular stent impregnated with rapamycin, alone or in combination with mycophenolic acid, during balloon catheterization to provide localized effects immediately following injury."); col. 12:29-35 ("A method of treating restenosis in a mammal . . . which comprises administering an antirestenosis effective amount of rapamycin to said mammal . . . via a vascular stent impregnated with rapamycin."); col. 12:36-42.

Morris '182: Page 3:24-27 ("This invention provides a method of preventing or treating hyperproliferative vascular disease in a mammal in need thereof by administering an antiproliferative effective amount of rapamycin to said mammal . . . via a vascular stent impregnated with rapamycin."); p. 7:27-29 ("Rapamycin, alone or in combination with mycophenolic acid can be administered intravascularly or via a vascular stent impregnated with rapamycin, alone or in combination with mycophenolic acid, during balloon catheterization to provide localized effects immediately following injury."); p. 7:57-8:1 ("Use as claimed in Claim 1 in which the medicament is adapted for administration . . . via a vascular stent impregnated with rapamycin."); p. 8:8-9 ("A use or product according to any one of Claims 1 to 4 wherein the hyperproliferative vascular disease is selected from intimal smooth muscle cell hyperplasia, restenosis, and vascular occlusion."); col. 8:15-16.

Myler '563: Abstract; col. 1:11-12 ("The present invention relates to cardiovascular stents which can be inserted into a body lumen."); col. 2:20-22; col. 2:53-58; col. 3:13-15; col. 4:56-57; col. 5:24-26 ("One purpose of the temporary stent is to modify the healing response to prevent re-occlusion of the artery (restenosis)."); col. 12:28-33; 12:63-65; col. 19:18-30 ("A tubular stent for implantation within a body lumen . . ."); col. 20:33-49; col. 20:51-52.

Palmaz '417: Abstract; col. 1:17-23 ("The invention relates to an expandable intraliminal graft for use within a body passageway or duct and, more particularly, expandable intraliminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease; and a method and apparatus for implanting expandable intraliminal grafts."); col. 4:25-37; col. 5:1-20; col. 5:26-43; col. 6:20-54; col. 11:3-34; col. 13:20-40; col. 14:39-59; col. 15:19-40; col. 15:53-16:5; col. 16:18-34; col. 16:43-63.

Aebischer '486: Abstract; Fig. 1; col. 3:19-23; col. 3:56-63; col. 5:29-43; col. 6:39-40; col. 8:1-30; col. 9:18-10:3.

Folkman '560: Col. 2:43-68; col. 3:18-23; col. 6:61-7:2; col. 10:11-14; col. 11:41-47; col. 11:56-12:20.

Schiraldi '243: Abstract; col. 1:8-21; col. 2:21-25 ("It is an object of this invention to provide an extruded film that is an effective and convenient intra-oral drug delivery system and method for applying and delivering controlled dosages of therapeutic agents into the oral cavity."); col. 2:30-51; col. 9:36-55.

Valentini '029: Abstract ("Medical devices employing semipermeable materials, such as acrylic copolymers, polyurethane isocyanate, and other biocompatible semipermeable polymers, are disclosed for use as guidance channels in regenerating nerves."); col. 2:29-57; col. 6:14-42.

Greco '135: Col. 3:8-19 ("An object of the present invention is to provide improved surfactant-modified implantable devices having a drug, including antibiotics, antithrombogenic agents, thrombolytic agents, disinfectants, etc., bound to the surface thereof."); col. 3:48-4:1; col. 9:10-12; col. 9:25-26.

Bawa '279: Col. 2:8-15 ("Another object is to provide a sustained-release polymeric hydrogel dosage form that is useful for topical, systemic or transdermal administration of medicinal agents, particularly ophthalmic drugs. A further object is to provide a polymeric matrix which is moldable to any desired shape, with moldability to the shape of the cornea of the eye being of major interest."); col. 8:50-53.

Wood '066: Abstract ("A controlled-release bandage containing therapeutic agents in a poly(vinyl alcohol) cryogel is disclosed. The bandage may include . . . hydrophobic particles to further insure controlled and constant release of therapeutic agents."); col. 2:56-66 ("Bandages comprising cryogel and therapeutic agents are used to provide a protective covering and to provide a controlled and uniform administration of therapeutic agents to sites of trauma such as wound, thermal or chemical burns, ulcers, lesions or surgical sites. Cryogel bandages may include . . . particles having hydrophobic properties, which absorb the therapeutic agent and release it in an uniform and controlled manner."); col. 2:67-3:10; col. 23:4-11.

Strecker '746: Abstract ("The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:56-2:2; 2:12-15; col. 2:21-32; col. 5:34-54; col. 6:59-62; col. 7:16-35; col. 8:19-10:19.

Lambert '246: Abstract; col. 2:15-34; col. 3:55-4:35; col. 10:45-61; col. 11:34-12:12; col. 12:15-52.

Bellamkonda '029: Abstract; Fig. 6; col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 4:9-14; col. 10:64-11:13; col. 11:33-40; col. 12:17-25; col. 19:33-22:37.

Dayton '382: Abstract ("A minimally invasive bioactivated endoprosthesis device for vessel repair. The device comprises a stent which is formed from metal or polymers into a predetermined shape which includes a plurality of holes . . . to provide a desired bending modulus."); col. 1:9-17 ("The present invention relates to an improved percutaneously inserted endoprosthesis device which is permanently or temporarily implanted within a body vessel, typically a blood vessel."); col. 3:62-4:17; col. 5:50-53; col. 8:4-33.

Burt '036: p. 4:19-33; p.10:17-25; p.14:9-27 ("As noted above, anti-angiogenic compositions of the present invention comprise an anti-angiogenic factor and a polymeric carrier. In addition to the wide array of anti-angiogenic factors and other compounds discussed above, anti-angiogenic compositions of the present invention may include a wide variety of polymeric carriers, including for example both biodegradable and non-biodegradable compositions."); p.21:2-4; 21:25-22:6.

Goldin '568: Abstract; col. 1:43-62; col. 2:1-6 ("In other instances, among them the release from the walls of cylindrical nerve guide tubes of trophic factors believed to aid nerve regeneration . . . it may be desirable for such an implantable delivery device to slowly decompose in vivo."); col. 2:24-29; col. 4:48-57 ("A preferred embodiment entails implantation of the device at or near the target of the desired therapeutic effect."); col. 10:55-58; col. 11:6-9; col. 23:6-26:5.

Palmaz '665: Abstract ("An expandable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 1: 11-17; col.2:64-3:7.

Palmaz '762: Abstract ("An expandable and deformable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 1:19-25; col. 4: 6-19.

Palmaz '337: Abstract ("An expandable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 1: 24-30; col. 3: 1-12.

Zaffaroni '254: Abstract ("A drug delivery device for administering a drug at a controlled rate for a prolonged period of time to produce a local or systemic physiological or pharmacological effect is comprised of a wall surrounding a reservoir containing a drug."); col.

4: 15-17 ("FIG. 4 is a side, fragmentary view depicting an anal drug delivery device of the invention for releasing drug in a body orifice."); col. 4: 21-28; Figures 4 and 6; col. 5: 65-68; col. 7: 1-5.

Aebischer: p. 283 (disclosing use of ethylene-vinyl acetate copolymer), p. 284-5 (disclosing implantation into human or animal tissue to promote nerve regeneration).

Dev: p. 273-74 (disclosing implantation of a polymer-coated stent capable of releasing treatment material).

Claim 15 [15B] (cont'd): providing a device comprising, a layer of flexible material that is minimally porous to macromolecules, said layer having a first and second major surface, the layer being capable of shaping in three dimensions by manipulation by human hands;

Where Found in the Prior References

Peterson '166: Col. 2:51-54 ("Typical polymeric carriers are polyesters, polyamides, polyurethanes and other condensations polymers . . .").

Schwartz '823: Abstract ("The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen."); Figs. 6-9, 13, 15; col. 1:9-14; col. 1:17-19; col. 1:53-55; col. 2:16-19 ("It is therefore an object of the present invention to provide a stent having longitudinal flexibility which allows it to conform to curves and variation in body lumens."); col. 2:29-40; col. 2:44-49; col. 2:49-53; col. 3:48-57; col. 3:58-61 ("The improvement of the present invention includes applying to the above-mentioned type of stent a flexible or elastomeric polymeric film which extends between the metal elements."); col. 3:64-4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof."); col. 4:20-27; col. 4:49-5:41; col. 5:64-6:1; col. 6:17-20; col. 6:30-32; col. 6:43-47; col. 49-52; col. 6:58-68 ("The flexible film can be applied as a sheath to the metal stent elements after which the stent can be compressed, attached to a catheter, and delivered through the body lumen to a desired location."); col. 7:25-8:11 ("The resulting stent has microcapsules containing one therapeutic substance on the inside (and able to contact blood once implanted in a blood vessel) and microcapsules containing a second therapeutic substance on the outside (and able to contact the vessel wall when implanted in contact with the vessel wall."); col. 8:19-41.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has

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been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); Fig. 3; col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-29; col. 5:34-6:29; col. 6:37-41; col. 6:41-45 ("Modifications of the polymer coating include a ring that encompasses the proximal portion of the stent, single or multiple strips that cover a portion of the stent, or a polymer coating with perforations."); col. 7:55-59; col. 8:23-60 ("Ethylene vinyl acetate copolymer (EVA) (Catalog #34,691-8) was obtained from Aldrich Chemical Company, Inc. (Milwaukee, Wis.); col. 10:24-33; col. 12:1-6; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow Controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Fig. 3; col. 1:7-10 ("This invention relates generally to expandable intraliminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:15-19 ("Ideally, implantation of such stent is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 1:57-60 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member."); col. 1:64-2:2 ("The polymer material can be a thermoplastic or an elastomer, for example, so that the film can stretch or deform radially when the stent structural member is expanded. The film of polymer material can be formed as a solid sheet, or can incorporate holes of various sizes and shapes to promote rapid endothelialization."); col. 2:23-33; col. 2:48-55; col. 4:15-24; col. 4:25-46; col. 4:47-5:3; col. 5:4-10; col. 5:49-6:25 ("The polymeric material is preferably selected from thermoplastic and elastomeric polymers. . . . In another currently preferred embodiment, the polymeric material can be ethylene vinyl acetate (EVA) . . ."); col. 6:26-65; col. 6:66-col.7:7; col. 7:18-21 ("The apertures also improve the flexibility of the polymeric material, allowing the stent segment to be more easily rolled and

uncoiled during expansion of the stent structural member . . ."); col. 7:23-42; col. 7:63-65; col. 8:12-57; col. 9:5-12; col. 10:12-30; col. 10:40-47.

Wolff '208: Col. 2:7-16 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); 2:28-30 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 6:59-62 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously. The polymer may be biostable or bioabsorbable. If biostable, the drug would diffuse out of the polymer."); col. 6:64-67 ("The variations of design shown in the embodiments of Figs. 1 and 2 show that the prosthesis of the invention must be secured against a lumen wall and must carry a drug-eluting polymer."); col. 7:59-61; col. 9:23-33 ("That layer may be a simple barrier which limits diffusion of drugs in the polymer. In that event, the smaller molecules could elute out immediately, while larger compounds would not elute until later when the layer has biodegraded."); col. 9:39-42 ("The device is fixed into place either by radial expansion in devices such as shown in Fig. 1 or are deformed by a balloon catheter in the case of devices in accordance with Fig. 2."); col. 10:3-45 ("The stents are arranged on the distal end of the catheter such that the catheter can provide remote, transluminal deployment of the stents, with the metal stent inside the polymeric stent, from an entry point into a selected portion of the body lumen to be treated and also remote actuation of an expansion mechanism from the proximal end of the catheter. The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen."); col. 10:51-57; col. 10:66-11:3 ("The metal stent is crimped onto the balloon and includes an elongated lead extending to the proximal end of the catheter assembly where it includes an enlarged portion to enable an operator to securely grip the lead."); col. 11:50-53 ("(b) a body including a plurality of support elements forming an open-ended, radially expandable, self-supporting tubular structuring having an interior surface and an exterior surface."); col. 12:1-15; col. 12:37-40 ("8. The device of claim 1 also comprising a barrier coating of polymeric material on the drug-containing filament to limit the rate of drug elution.").

Berg '354: Page 2:14-15 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen."); p. 2:43-54 ("Viewed from a further aspect the invention provides the use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug-eluting surface coating."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p.3:18-22 ("The transluminal delivery can be accomplished by a catheter designed for the delivery of stents and the radial expansion can be accomplished by balloon expansion of the stent, by self-expansion of the stent, or a combination of self-expansion and balloon expansion. Thus the present invention

provides a stent which may be delivered and expanded in a selected blood vessel without losing a therapeutically significant amount of a drug applied thereto."); p. 3:29-31 ("Also, stents made with biostable or bioabsorbable polymers such as poly(ethylene terephthalate), polyacetal, poly(lactic acid), poly(ethylene oxide)/poly(butylene terephthalate) copolymer could be used in the present invention. "); p. 3:33-34 ("Both the inner and outer surfaces of the stent may be provided with the coating according to the present invention."); Table 1; p. 4:5-24; p. 5:28-29; p. 6:6-11; p. 6:15; p. 6:24-35; p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Col. 1:58-60; col. 2:16-17; col. 3:21-25 ("The tubular main body includes an outer surface and inner surface. The outer surface of the main body faces an inner surface wall of the vessel. The inner surface of the stent faces a stream flowing through the lumen as shown in cross section in Fig. 2."); col. 4:1-5 ("In one embodiment, the main body includes a film that is preferable combined with the plurality of fibers disposed around the main body. The film combined with the plurality of fibers defines the outer surface of the main body."); col. 4:15-16 ("Preferable, the main body of the stent includes a film covering the inner surface."); col. 4:19-22 ("Additionally, the present invention includes an embodiment where the inner surface and the outer surface of the main body are separated by at least one interior film layer."); col. 5:23-33 ("For instance, in one embodiment, the film and fibers covering the inner surface of the main body of the biodegradable stent The film covering the outer surface along with the plurality of fibers"); col. 4:46-64; col. 5:11-20; col. 6:49-59; col. 7:10-20 (" . . . said tubular main body including a slot extending lengthwise through the main body and defined by opposing edges of the main body wherein the opposing edges must be moved toward each other under compression in order to transport the biodegradable stent through a vessel of a living being . . ."); col. 7:27-29; col. 8:18-24; Fig. 2.

Ding '536: Abstract ("The coating includes a relatively thin layer of biostable elastomeric material containing an amount of biologically active material, particularly heparin, dispersed in the coating in combination with a non-thrombogenic surface."); col. 1:24-29 ("The present invention relates generally to providing biostable elastomeric coatings on the surfaces of implants which incorporate biologically active species having controlled release characteristics in the coating particularly to providing a non-thrombogenic surface during and after timed release of the biologically active species."); col. 1:48-51 ("One type of self-expanding stent has a flexible tubular body formed of several individual flexible thread elements each of which extends in a helix configuration with the centerline of the body serving as a common axis."); col. 3:5-9; col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 3:56-64 (" . . . the tubular body is formed of a self-expanding open braid of fine, single or polyfilament metal wire which flexes without collapsing, readily axially deforms to an elongate shape for transluminal insertion via a vascular catheter and resiliently expands toward predetermined stable dimensions upon removal in situ."); col. 5:10-56 ("Polymers generally suitable for the undercoats or underlayers include silicones (e.g., polysiloxanes and substituted polysiloxanes), polyurethanes, thermoplastic elastomers in general,

ethylene vinyl acetate copolymers, polyolefin elastomers, polyamide elastomers, and EPDM rubbers. The above-referenced materials are considered hydrophobic with respect to the contemplated environment of the invention."); col. 12:62-13:2; col. 13:13-26; col. 13:37-40; col. 14:5-17; col. 14:22-34.

Dinh '227: Figs. 1, 9, 10; col. 1:32-35 ("The stent is typically inserted by catheter into a vascular lumen told [sic] expanded into contact with the diseased portion of the arterial wall, thereby providing mechanical support for the lumen."); col. 2:51-54 ("To accomplish this while not affecting the strength of the overall fibrin stent structure, a first layer is applied to a stent body, the first layer incorporating a polymer and the therapeutic substance."); col. 2:62-66 ("The inclusion of a polymer in intimate contact with a drug on the underlying stent structure allows the drug to be retained on the stent in a resilient matrix during expansion of the stent and also slows the administration of drug following implantation."); col. 3:10-14; col. 3:14-22; col. 3:25-38; col. 5:3-7; col. 5:44-55; col. 5:56-57; col. 6:13-19 ("In U.S. Pat. No. 4,548,736 issued to Muller et al., a dense fibrin composition is disclosed which can be a bioabsorbable matrix for delivery of drugs to a patent. Such a fibrin composition can also be used in the present invention by incorporating a drug or other therapeutic substance useful in diagnosis or treatment of body lumens to the fibrin provided on the stent."); 6:50-56 ("Alternatively . . . a dense fibrin composition suitable for drug delivery can be made without the use of microcapsules by adding the drug directly to the fibrin followed by compression of the fibrin into a sufficiently dense matrix that a desired elution rate for the drug is achieved."); col. 6:62-67; col. 7:10-13; col. 7:13-2; col. 7:56-64 ("In another embodiment of the invention, the coating of polymer and drug on the stent is achieved by forming a first fibrin layer on the stent body which incorporates the therapeutic substance and then applying a second layer of fibrin."); col. 8:49-52 ("A catheter has a balloon upon which a stent has been placed, the stent having a deformable metal portion and a fibrin coating, thereon."); col. 8:52-60 ("Fig. 2 shows an alternative stent in which a fibrin film has been affixed to the underlying metallic framework by affixing it to the stent . . ."); col. 8:64-9:3; col. 9:18-24; col. 9:49-50 ("The resulting fibrin stent includes the stent embedded in a very thin elastic film of fibrin."); col. 9:59-63; col. 12:24-28; col. 12:38-50.

Domb '055: Abstract ("Devices are provided having a polymer coating incorporating compounds inhibiting inflammation and infection, along with subsequent tissue growth onto and around the device. . . . Preferred polymeric coating are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); col. 1:12-15 ("This invention relates to invasive medical devices for delayed/sustained release of pharmaceutical compositions from a polymer that is coated or incorporated into the devices."); col. 3:54-57 ("In the preferred embodiments, these have utilized bioerodible polymers as the matrix for the drug to be released, usually as a function of diffusion and erosion of the polymer."); col. 4:22-36; col. 5:24-37 ("In a particularly preferred embodiment, polymers incorporating steroids are coated onto devices including tracheal T-tubes, stoma stents, laryngeal/bronchial stents, laryngeal keels, and nasogastric tubes."); col. 5:41-45; col. 5:46-6:1; col. 6:24-26 ("Examples of suitable polymers include ethylene vinyl acetate, polyurethane, silicones, hydrogels, polyurethane, and polyvinyl chloride."); col. 7:10-20; col. 7:40-52; col. 9:15-30; col. 9:55-10:2; col. 10:21-52; col. 10:60-11:11; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the

solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 11:36-38 ("The medical device of claim 1, wherein the polymer is selected from the group consisting of polyurethane, ethylene vinyl acetate, silicones, hydrogels, and polyvinyl chloride."); col. 11:39-44; col. 12:11-22; col. 12:23-25; col. 12:26-31; col. 12:32-42.

Fox '096: Abstract ("A method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers, and antimicrobial agents . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 2:48-65; col. 3:55-67 ("The polymeric coating agent component of the coating vehicle of the present invention is selected from the group consisting of biomedical polyurethanes, biomedical silicones, biodegradable polymers and combinations thereof."); col. 3:55-67; col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages."); col. 19:11-16; col. 31:62-64.

Hunter '981: Fig. 14B, 17E; col. 1:12-17; col. 3:42-45 ("Within one aspect of the present invention, compositions are provided (anti-angiogenic compositions) comprising (a) an anti-angiogenic factor and (b) a polymeric carrier."); col. 3:53-61; col. 12:23-25 ("As noted above, the present invention provides compositions comprising an anti-angiogenic factor, and a polymeric carrier."); col. 16:31-56; col. 17:63-18:7 ("[T]he anti-angiogenic compositions of the present invention may be formed as a film. . . . Such films are preferably flexible with a good tensile strength . . . and has controlled permeability."); col. 22:3-7; col. 22:21-39; col. 22:40-64; col. 22:54-58; col. 23:26-30; col. 47:58-49:7; col. 52:4-8; col. 60:35-45; col. 66:13-22; col. 69:19-62; col. 84:62-86:24; 86:56-59; col. 87:11-22; col. 88:19-26.

Kowligi '782: Abstract ("The elastomeric coating is made of polyurethane or another biocompatible non-porous elastomers and precludes tissue ingrowth into the outer cylindrical wall, minimizes suture hold bleeding, and increases suture retention strength, while reducing the incidence of serous weepage."); Figs. 2 & 3; col. 1:18-26; col. 1:28-41; col. 1:42-64; col. 2:15-20; col. 2:38-47; col. 2:53-59; col. 2:60-3:4 ("PTFE tube 32 includes an inner cylindrical wall and an opposing outer cylindrical wall. As shown in Fig. 2, outer cylindrical wall is coated entirely around its circumference by a uniformly thick coating of a biocompatible elastomer."); col. 3:27-38; Figure 3; col. 4:1-5; col. 4:16-27 ("In regard to elastomeric coating 38 shown in

Fig. 2, such elastomeric coating is selected to be a biocompatible elastomers and may be selected from the group consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 4:28-37; col. 4:37-39 ("The elastomeric coating should also be sufficiently non-porous to preclude serous weepage and inhibit tissue ingrowth therethrough."); col. 4:64-66; col. 5:4-7; col. 7:49-8:9; col. 8:38-44; col. 9:65-10:6; col. 10:18-24; col. 10:33-42; col. 10:43-50; col. 10:51-59; col. 10:60-67.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 2:16-35; col. 2:40-50; col. 3:8-12; col. 3:29-32; col. 3:54-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); col. 5:57-61; col. 7:29-32; col. 8:1-6; col. 10:57-64; col. 11:49-51; col. 11:65-12:13; col. 12:43-64; col. 13:13-19.

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p. 3:10-31 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); p. 4:2-12; p. 6:21-28 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); p. 10:17-21; claim 1:1-14; claim 8:1-5; claim 10:1-3; claim 11; claim 22; claim 23:1-14; claim 19:4-31.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8.

Myler '563: Abstract; Figs. 1, 2, 13; col. 2:10-13; col. 2:13-16 ("The stent is configured to permit radial expansion, such as under the force generated by balloon dilation, and radial contraction in response to axial elongation."); 2:22-26; col. 2:27-28; col. 3:13-15; col. 3:33-34; col. 3:44-46; col. 3:48-51 ("Alternatively, tubular stents formed from flexible non-metal materials such as elastomeric polymers or rubber (latex) can also be radially reduced by axial elongation in accordance with the present invention."); col. 3:52-54; col. 3:58-61; col. 4:9-12; col. 4:30-43 ("In a preferred embodiment, the interior and exterior walls of stent 10 are enclosed in a thin polymeric envelope. . . . Suitable envelope materials include elastic materials such as latex and others that can be readily selected by one of skill in the art."); col. 4:53-56; col. 5:1-16;

col. 5:39-41 ("For the above reasons, even the expanded pores for drug delivery should be small enough to maximize or prevent cell penetration, but large enough for drug delivery."); col. 5:50-54; col. 11:63-65; col. 12:11-13; col. 12:19-23; col. 12:28-33 ("Suitable materials include elastomeric polymers or natural rubber (latex). . . . Polymeric stents can be provided with relatively fluid impenetrable walls, or porous walls such as to allow drug delivery, as will be apparent to one of skill in the art."); col. 12:54-62; col. 12:63-65 ("Suitable coating materials include elastic materials such as polyethylene or PET or other materials that can be readily selected by one of skill in the art."); col. 18:51-19:9; col. 19:18-30; col. 19:31-32; col. 19:61-63; col. 19:65-20:7; col. 20:51-57.

Palmaz '417: Fig. 1A, 1B, 3, 5, 6, 8; Col. 5:66-68 ("Figs 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon;"); col. 11:3-14 ("Examples of a suitable biologically compatible coating would be porous polyurethane, Teflon™ or other conventional biologically insert plastic materials."); col. 11:3-34 ("The coating should be thin and highly elastic so as not to interfere with the desired expansion and deformation of prosthesis, or graft. . . . Examples of biologically compatible coatings would include coatings made of absorbable polymers such as those used to manufacture absorbable sutures. Such absorbable polymers include polyglycoides, polyacoides, and copolymers thereof."); col. 13:22-24; col. 13:30-40.

Tice '330: Col. 3:20-33 ("Suitable wall forming materials include polystyrene, ethylcellulose, cellulose acetate, hydroxyl propylmethylcellulose phthalate, cellulose acetate, dibutylaminohydroxypropyl ether, polyvinylbutyral, polyvinyl formal, poly(meth)acrylic acid ester, polyvinylacetal-diethylamino acetate, 2-methyl-5-vinyl pyridine methacrylate-methacrylic acid copolymer, polycarbonate, polyesters, polypropylene, vinylchloride-vinylacetate copolymer, polysaccharides, glycerol distearate, and the like. A preferred group of polymeric wall forming materials includes those which are biodegradable such as aliphatic polyesters including polylactide, polyglycolide, polycaprolactone and copolymers thereof."); col. 8:38-51.

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); Figs. 1 & 2; col. 3:7-18; col. 3:56-63; col. 4:31-34 ("The outer membrane surface is nonporous, while porous inner membrane surface allows for the diffusion therethrough of active factor 26."); col. 5:18-28 ("In a preferred embodiment of the invention, the outer surface of the membrane is impermeable to solutes of any size, while the inner membrane surface contains pores [that] enable the active factors to diffuse out of the membrane and into the lumen of the channel."); col. 6:17-22 ("The layering procedure allows deposition of an impermeable coat on the outer surface of the device, insuring that the active factors incorporated into the membrane walls will be inhibited from diffusing through the external surface, and will diffuse only through the inner membrane surface into the lumen of the channel."); col. 6:54-61; col. 9:18-10:3.

Folkman '560: Col. 2:43-68 ("A biocompatible plastically deformable polymer matrix . . . substantially impermeable to a macromolecule"); col. 3:18-23 ("The polymer matrixes, which are suitably used in the present invention, are biocompatible in the environment of use,

plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:36-51 ("Typical polymeric material suitable for forming the matrix . . . include . . . alkylene-vinyl acetate copolymers . . . crosslinked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:52-4:26 ("In the presently preferred embodiment the polymeric materials useful for forming the matrix are the ethylene vinyl ester copolymers of the general formula . . ."); col. 11:56-12:20.

Cohen '496: Col. 3:26-45 ("The polymer matrices . . . are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 9:40-10:17; col. 10:18-32.

Schiraldi '243: Col. 1:8-21 ("The extruded film drug delivery system of the present invention, which has incorporated therein the medicament to be dispensed, is so thin and flexible when wet as to be unobtrusive to the patient after it has been properly positioned and placed in the mouth."); col. 1:58-60; col. 2:30-51; col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. . . . The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 9:36-55; col. 10:12-18; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Valentini '029: Abstract ("Medical devices employing semipermeable materials, such as acrylic copolymers, polyurethane isocyanate, and other biocompatible semipermeable polymers, are disclosed for use as guidance channels in regenerating nerves. . . . The guidance materials are chosen such that they are capable of allowing the diffusion of nutrients and other metabolites to the regenerating nerve site while excluding fibroblasts and other scar-forming cells."); Fig. 3; col. 1:56-2:4; col. 2:29-57 ("It has been discovered that the repair of severed or avulsed nerves can be greatly enhanced by the use of selectively permeable polymeric materials as nerve guidance channels. . . . The devices can be formed from various polymeric materials, such as acrylic copolymers, polyvinylidene fluoride or polyurethane isocyanate Preferable, the materials allow passage therethrough of solutes having a molecular weight of about 100,000 daltons or less. . . . The nerve guidance channels of the present invention are also preferably designed to retain nerve growth factors secreted at the anastomatic site or seeded therein, as well as retain any luminal matrix material placed inside the guidance channels."); col. 2:58-3:14; col. 3:62-67; col. 4:46-59; col. 5:13-32 ("The success rate and quality of peripheral nerve regeneration was dramatically enhanced through the use of a semipermeable material."); col. 5:33-41; col. 5:42-6:12 ("The permselective characteristics of the inner membrane allow the exchange of nutrients, while concentrating growth factors released by the nerve and excluding scar-forming cells."); col. 6:14-24; col. 6:31-42.

Greco '135: Col. 3:48-4:1 ("These devices will consist of organic polymers and/or metallic materials including: . . . polyethylene . . . elastomeric organosilicon polymers, such as polysiloxanes, e.g. Silastic ®").

Aebischer '627: col. 3:57-4:3 ("The polymeric insert includes pores having a molecular weight exclusion of from about 1 kD to about 1,000 kD, but preferably from about 25kD to about 100 kD."); col. 4:11-27 ("The terms 'semipermeable' is used herein to describe biocompatible membranes that allow the diffusion therethrough of molecules having a relatively low molecular weight, while excluding the passage of those having a relatively high molecular weight. . . . The semipermeable membrane can be made of various polymeric compositions such as polyvinylchloride, polyacrylonitrile, polyvinylidene fluoride, polystyrene, polymethylmethacrylate, polysulfone, and acrylic copolymers."); col. 7:57-8:14 ("In this embodiment, a semi-permeable membrane functions as a protective cell culture device for the neurotransmitter-secreting cells. The pores of the membrane should be large enough to enable the exchange of metabolites with body fluids, and to permit the diffusion therethrough of neurotransmitter produced by the cells therein, but are small enough to bar the passage therethrough of larger elements deleterious to the cells."); col. 13:31-48; col. 13:66-68; col. 14:1-2; col. 14:22-28; col. 14:54-56.

Bawa '279: Col. 6:50-57 ("Alternatively, a two layer system may be formed having one layer as polymer plus drug and the other layer as drug-free polymer.").

Wood '066: Abstract ("A controlled-release bandage containing therapeutic agents in a poly(vinyl alcohol) cryogel is disclosed. The bandage may include . . . hydrophobic particles to further insure controlled and constant release of therapeutic agents."); col. 2:56-3:17; col. 7:51-65; col. 17:19-22; col. 17:30-34 (" . . . to give a flexible, elastomeric, white cryogel membrane . . ."); col. 18:1-4; col. 18:13-16; col. 18:26-30; col. 23:4-11.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); Figs. 4, 7, 8; col. 1:12-22 ("Once correctly positioned it will expand from an initial state with a narrow lumen into a state with a lumen that is as wide as its placement will allow. . . . The lumens can be expanded by mechanically stretching them with a known balloon catheter. They can also be compressed prior to implantation and stretch out on their own subject to the resilience introduced by the compression."); col. 1:63-2:2; col. 2:12-15 ("The present invention on the other hand exploits a wrapping material that plastically deforms as it expands . . ."); col. 2:21-32; col. 2:33-38; col. 2:59-64; col. 2:65-3:4; col. 3:7-16; col. 3:27-33 ("The lining can to advantage be made of polymers or compounds thereof."); col. 3:51-62; col. 3:63-4:31 ("It can be of advantage for the lining to be of several layers, each impregnated with different medications. . . . It has also been demonstrated practical for the inner layer of the lining to be impregnated with antithrombotics and the outer with antiproliferatives and/or other medicational substances."); col. 5:18-20 ("Fig. 4 is a view similar to that of Fig. 2 of an endoprosthesis with a multiple-layer lining and with its ends coated with medication,"); col. 5:34-41 ("The endoprosthesis . . . is completely enclosed in an inner lining component and an outer lining component."); col. 5:49-54

("The thread itself in an endoprosthesis of the type illustrated in Fig. 3 can also be wrapped in a coat of medicated and biodegradable wrapping material. . . . The prosthesis can of course alternatively be enclosed in a flexible-tubular coat."); col. 5:55-64; col. 6:30-44; col. 6:50-55; col. 6:59-62; col. 7:16-35; col. 7:48-65; col. 8:4-8; col. 8:10-10:19.

Lambert '246: Abstract ("Thus, a polyurethane coating is applied to a prosthetic article, the coating then swelled . . . so that substantial quantities of biologically active compounds can be incorporated within the interstices of the polymer."); col. 2:15-34; col. 2:40-49; col. 2:53-65; col. 3:55-4:35 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility to as to enable the application of a stable coating onto substrate (i.e. the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected)."); col. 10:45-67; col. 11:34-59; col. 12:15-41.

Bellamkonda '029: Abstract ("A nerve guidance channel for use in regenerating severed nerve is prepared containing a tubular semi-permeable membrane having openings adapted to receive the ends of a severed nerve, and an inner lumen containing the matrix having an adhesive peptide fragment through which the nerve can regenerate."); Fig. 6; col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 4:9-14; col. 4:21-39 ("Any suitable hydrogel may be used as the substrate for the bioartificial extracellular matrices of this invention."); col. 4:48-57; col. 5:10-14 ("Several physical properties of the hydrogel matrices of this invention are dependent on gel concentration. Increase in gel concentration may change the gel pore radius, morphology, or its permeability to different molecular weight proteins."); col. 7:13-25; col. 10:28-40 ("Permselective channels with a molecular weight cut-off of 50,000 daltons allowed regeneration of nerves in a mouse sciatic nerve model."); col. 10:41-63; col. 10:64-11:13; col. 11:33-40; col. 12:13-16 ("Preferably the permselective membrane is fabricated to be impermeable to some of these substances so that they are retained in the proximity of the regenerating nerve ends."); col. 12:17-25 ("Briefly, various polymers and polymer blends can be used to manufacture the nerve guidance channel."); col. 12:42-49; col. 19:7-16; col. 23:54-24:55.

Dayton '382: Abstract ("The device comprises a stent which is formed from metal or polymers into a predetermined shape which includes a plurality of holes . . . to provide a desired bending modulus. The stent is then coated with a polymer . . . which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids, with the equilibrium being controlled by charge distribution, concentration and molecular weight of the bioactive substance in relation to the pore size of the polymeric carrier for controlled prolonged release of said bioactive substance."); Figs. 4, 7, 9, 10, 12, 14; col. 3:62-4:17 ("Among these polymers are polymers having a microporous structure, such as . . . biodegradable polylactic acid polymers, polyglycolic acid polymers . . ."); col. 4:24-33 ("A bioactive substance is preferably admixed in the polymer for elution from the microporous structure of the stent or coating on the stent after implantation. The rate of elution of the bioactive substance is controlled by selecting a pore size for microporous structure . . ."); col. 4:42-50; col. 4:54-5:3; col. 6:64-7:7 ("The

polymer should have a microporous structure with a predetermined pore size."); col. 8:18-33 ("a polymer forming the exterior surface of said stent for operative contact with said tissue . . ."); col. 8:42-59; col. 8:66-9:5; col. 10:1-2.

Burt '036: Fig. 14B; p. 4:19-33 ("Similarly a wide variety of polymeric carriers may be utilized, representative examples of which include poly(ethylene-vinyl acetate) . . . and copolymers of polylactic acid and polycaprolactone."); p. 10:17-25; p. 14:9-27 ("As noted above, anti-angiogenic compositions of the present invention comprise an anti-angiogenic factor and a polymeric carrier. In addition to the wide array of anti-angiogenic factors and other compounds discussed above, anti-angiogenic compositions of the present invention may include a wide variety of polymeric carriers, including for example both biodegradable and non-biodegradable compositions."); p. 21:2-4; p. 21:25-22:6 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size."); p. 51:1-52:35.

Goldin '568: Figs. 1A, 5A-5F; col. 1:43-62 ("Release by controlled diffusion may be accomplished by means of containment of the therapeutic agent within a substrate whose small pore size and/or tortuosity of diffusion path thereof limits the diffusion of said agent through the substrate. . . . The therapeutic agent can be incorporated within the diffusion-limiting substrate . . . Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:8-12; col. 2:24-29 ("Microporous membranes for release of proteins by controlled diffusion have been fabricated from ethylene vinyl acetate (EVA), and said membranes have been used in vivo in a manner which demonstrates their therapeutic potential."); col. 5:28-34 (" . . . underlayment material of controlled pore size can be created and used to fabricate a device of optimal porosity . . . and accessibility of the releasable macromolecule to biological material at or beyond the membrane's external surface . . ."); col. 11:58-12:14; col. 13:53-65; col. 14:1-28; col. 14:66-15:67; col. 31:57-32:7 ("The device of claim 1 wherein said microporous underlayment comprises a polymer."); col. 32:16-22.

Palmaz '665: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); Figures 5 and 6; col. 3:20-25 ("The present invention includes a tubular shaped member having first and second ends and a wall surface disposed between the first and second ends..."); col.3:47-51 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5:30-32 ("FIGS. 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon."); col. 5:58-63; col. 4:24-28.

Palmaz '762: Col. 3:34-37("The present invention includes a tubular shaped member having first and second ends and a wall surface disposed between the first and second ends..."); 3:65-4:2 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 4:43-46; col. 6:9-13; col. 9:20-25; col. 10:28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a

biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '337: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col. 3:27-30 ("The present invention includes a tubular shaped member having first and second ends and a wall surface disposed between the first and second ends..."); col.3:52-56 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 4: 29-34; col. 5:19-21; Figures 5 and 6; col. 8:28-32; col. 9:24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials."); col. 5:65-6:2.

Zaffaroni '254: Abstract ("The wall is formed in at least a part of a microporous material..."); col. 1:19-23 ("The wall of the device is comprised in at least a part of a microporous material..."); col. 3:5-10; col. 3:42-45 ("In accomplishing these objects and advantages of this invention, one feature of the invention, in its broadest aspect resides in a novel drug delivery device comprising a wall enclosing a reservoir."); col. 3:48-53; col. 4:41 ("Drug delivery device 10 is comprised of a wall 11..."); col. 4:47-54 ("Wall 11 is formed of a microporous material the micropores 15 of which contain a drug release rate controlling medium, not shown, permeable to the passage of drug, as by diffusion, or by convection, or by a concurrent operation of both, but the rate of passage of the drug through the medium in the micropores is lower than the rate of passage of drug through the solid drug carrier."); col. 5:3-11; col. 6: 27-30.

Engelberg & Kohn: p. 298; p. 299 ("Whilst L-PLA showed a purely elastic deformation for most of the stress-strain curve, D,L-PLA was more ductile and exhibited a significantly larger proportion of plastic deformation."); p. 301 ("Compression moulding [of PCL] yielded opaque, flexible films.") ("Transparent films [of PTMC] were readily obtained by compression moulding at 40 °C using a low load of 0.5 tonnes. The films could be rolled up and deformed without breaking.").

Aebischer: p. 283 (disclosing preparation of polymer tube made of ethylene-vinyl acetate copolymer); Fig. 2A (disclosing one major surface facing the nerve stumps and another major surface facing away from the nerve stumps); p. 284 (disclosing manipulation of polymer tube to allow entry of nerve stumps).

Dev: p. 273 ("We used a commercially available biomedical grade polyurethane Tecoflex is a biocompatible, flexible, and an elastic membrane-forming polymer.").

Claim 15 [15C] (cont'd): the first major surface of the layer being adapted to be placed adjacent to a damaged tissue,

Where Found in the Prior References:

Schwartz '823: Abstract ("The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen."); Figs. 6-9, 13, 15; col. 2:37-40 ("In essence, this improvement makes it possible to provide a stent able to support body lumens and conform to curves or irregularities in body lumens."); col. 2:44-54 ("The composite stent of the present invention can be delivered to the site of the occlusion by catheter and expanded conventionally, causing the film to expand or open radially along with the metallic elements of the stent and to be brought into contact with the body lumen. The polymeric film is flexible and preferably an elastic or stretchable film that is capable of conforming to the movement of the metallic stent elements when expanded into contact with a body lumen."); col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:48-54; col. 3:58-col. 4:6; col. 6:49-52 ("As shown in Fig. 13, the stent can be delivered to the body lumen and expanded (e.g. by use of a balloon catheter) into contact with the body lumen."); col. 6:33-37 ("As shown in Fig. 9, with the angioplasty procedure completed, balloon is deflated and withdrawn leaving stent firmly implanted within vessel with the film held in contact with the vessel."); col. 6:62-68 ("Once in the desired location, the stent can be released from the catheter and expanded into contact with the lumen as shown in Fig. 15 where it can conform to the curvature of the body lumen. The flexible film is able to form folds which allow the stent elements to readily adapt to the curvature of the body lumen.").

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14 ("The present invention satisfies this need by providing a separate sleeve to encompass the stent and serve as a local drug delivery device to prevent thrombosis."); col. 4:53-55 ("The present invention satisfies this need by providing a separate sleeve to encompass a stent to locally administer drugs to prevent restenosis."); col. 4:58-68 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. . . . Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a

stent encompassed by the sheath of the invention into a vessel of the subject."); col. 5:26-29; col. 6:49-55 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface); col. 8:8-22; col. 8:58-60 ("The films were placed to line the circumference of a 2 cm length of ePTFE grafts, over which a 2 cm long stent was deployed."); col. 9:12-16 ("In addition, polymer-drug films which prevent thrombosis in the baboon and pig AV shunt system can be studied following stent-film placement in carotid, superficial femoral and coronary arteries following balloon injury of those vessels."); col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Fig. 8; col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:12-20 ("Stents are typically implanted within a vessel in a contracted state and expanded when in place in the vessel in order to maintain patency of the vessel to allow fluid flow through the vessel. Ideally, the implantation of such stents is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:50-56 ("The stent can be used in coronary arteries or any other part of the vasculature or other body lumen where mechanical opening force is necessary or desirable to keep the vessel open or to maintain the stent flush against the lumen wall, and where an anti-restenosis, anti-proliferative or other types of therapeutic drug or agent is to be simultaneously positioned and diffused."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably

loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 2:23-33; col. 5:15-17; col. 7:56-62; col. 9:63-67 ("The deployment of the stent can also be improved by . . . decreasing friction between the vessel or lumen wall and the stent."); col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:52-54 ("The invention provides prostheses which may be inserted into a lumen of a body and fixed to the lumen wall adjacent an area needing treatment."); col. 1:63-66 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery."); col. 2:7-9 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:25-27 ("The current invention contemplates the usage of any prosthesis which elutes drugs locally to treat a lumen in need of repair."); col. 6:36-38; col. 6:56-58 ("The stent shown in Figs. 2 and 4 is a metallic malleable design which may be forced against a lumen wall by a balloon catheter which fixes it into position."); col. 6:64-67 ("The variations of design shown in the embodiments of Figs. 1 and 2 show that the prosthesis of the invention must be secured against a lumen wall and must carry a drug-eluting polymer."); col. 9:67-10:3 ("By including a metal stent within the lumen of the polymeric prosthesis, the polymeric prosthesis is effectively held against the wall of the body lumen by the strength of the metal stent."); col. 10:23-38 ("The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen. This will bring the bioabsorbable element into supporting contact with a body lumen at an interior position of the body lumen to be treated and will position the bioabsorbable element to deliver drugs to the body lumen. Following the expansion of the stents into luminal contact, the balloon (if the expansion device is a balloon) can be deflated which allows the luminal flow to be restored."); col. 10:46-59; col. 11:10-13; col. 11:17-20; col. 11:50-53 ((b) a body including a plurality of support elements forming an open-ended, radially expandable, self-supporting tubular structuring having an interior surface and an exterior surface."); col. 12:1-15.

Berg '354: Page 2:14-18 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen. Examples of stents which have been successfully applied over a PTCA balloon and radially expanded at the same time as the balloon expansion of an affected artery include the stents disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) which are incorporated herein by reference in their entirety."); p. 2:34-36 ("Metal stents such as those disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) could be suitable for drug delivery in that they are capable of maintaining intimate contact between a substance applied to the outer surface of the stent and the tissues of the vessel to be treated."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution

which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:16-18 ("In operation, the stent made according to the present invention can deliver drugs to a body lumen by introducing the stent transluminally into a selected portion of the body lumen and radially expanding the stent into contact with the body lumen.").

Buscemi '450: Col. 3:14-15 ("The stent strengthens an area of the vessel that is in contact with the stent."); col. 3:21-25 ("The tubular main body includes an outer surface and inner surface. The outer surface of the main body faces an inner surface wall of the vessel. The inner surface of the stent faces a stream flowing through the lumen as shown in cross section in Fig. 2."); col. 4:61-64 ("The stent is secured by releasing the stent from compression so that the stent can radially spring out to abut against the inner surface wall of the vessel."); col. 6:49-52; col. 7:27-29; col. 8:9-11.

Ding '536: Col. 5:38-40 ("Surface material should minimize tissue rejection and tissue inflammation and permit encapsulation by tissue adjacent the stent implantation site.").

Dinh '227: Col. 1:32-35 ("The stent is typically inserted by catheter into a vascular lumen told [sic] expanded into contact with the diseased portion of the arterial wall, thereby providing mechanical support for the lumen."); col. 8:20-23 ("The term "stent" herein means any device which when placed into contact with a site in the wall of a lumen to be treated, will also place fibrin at the lumen wall and retain it at the lumen wall."); col. 8:37-43; col. 9:18-24 ("The stent is then delivered through the body lumen on the catheter to the treatment site where the stent is released from the catheter to allow it to expand into contact with the lumen wall.").

Domb '055: Abstract ("Preferred embodiments include catheters, tubes, and implants that abut tissue following implantation into the body . . ."); col. 4:25-32; col. 5:27-33; col. 5:49-54; col. 5:63-6:1 ("Coating that part of the tube, which is in contact with the mucosa, with the drug-loaded polymer provides a sustained release of steroids and antibiotics locally and at high concentration in the area which is critically affected, achieving the same effect as the systemic administration of the drugs without their side effects, throughout the duration of the intubation."); col. 6:8-18; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages.").

Kowligi '782: Abstract; col. 1:18-41; Figs. 2, 3; col. 10:18-67.

Hunter '981: Col. 4:24-38; col. 5:1-6; col. 16:31-56; col. 22:3-7; col. 22:54-58; col. 23:6-13 ("[M]ethods are provided for expanding the lumen of a body passageway, comprising inserting a stent into the passageway, the stent having a generally tubular structure, the surface of the structure being coated with an anti-angiogenic composition . . . such that the passageway is expanded."); col. 23:30-31; col. 23:46-51; col. 24:45-51; col. 24:66-25:5; col. 25:24-29; col. 25:48-54; col. 52:4-8 ("This film is designed to be placed on exposed tissue so that any encapsulated drug is released from the polymer over a long period of time at the tissue site."); 86:56-59; col. 87:11-22; col. 88:19-26.

Lambert '922: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion."); col. 3:54-61; col. 8:1-6.

Lambert '308: Page 3:24-27 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion.").

Myler '563: Col. 3:34-37 ("Stent 10 is illustrated in its expanded position at a treatment location adjacent vascular wall in an artery, in accordance with one aspect of the present invention."); col. 4:53-56 ("The exterior surface of the envelope which will contact the arterial wall is optionally made porous to enable the release of drugs from the envelope and/or stent to the treatment site."); col. 10:12-14 ("The balloon is inflated, thereby expanding the stent radially outwardly until it contacts either a previously dilated, or presently stenosed wall."); col. 10:56-61; col. 11:63-65 ("Once the stent has been positioned at the treatment site, axial elongating tension is released, and it is permitted to radially expand against the lumen wall."); col. 13:15-17 ("The exterior coating which will contact the arterial wall is optionally made porous to enable the release of drugs to the treatment site.").

Palmaz '417: col. 4:25-37 (" . . . expanding a portion of the catheter associated with the prostheses to force at least one of the prostheses radially outward into contact with the body passageway . . .").

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); Figs. 1 and 2; col. 9:18-10:3.

Strecker '746: Figs. 7 & 8.

Schiraldi '243: Col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of

aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consist of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Valentini '029: Abstract ("In particular, tubular channels which have a smooth inner surface and longitudinally oriented trabeculae result in significantly larger regenerated nerve cables and higher numbers of regenerated myelinated axons."); Figure 3; col. 2:32-35 ("Medical devices employing such selectively permeable materials, particularly semipermeable tubular devices having smooth inner skins, are disclosed for use in regenerating nerves."); col. 2:58-3:14; col. 5:33-41; col. 6:14-24.

Bawa '279: Col. 6:40-44; col. 12:29-34.

Wood '066: Col. 2:67-3:32 ("The object of this invention is to provide means for delivery effective dosages of therapeutic agents to sites of trauma such as wounds, thermal or chemical burns, ulcers, lesions, or surgical sites.").

Aebischer '486: Fig. 1.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:63-2:2; col. 2:21-32; col. 2:33-38; col. 2:39-46; col. 3:63-4:31 ("It can be of advantage for the lining to be of several layers, each impregnated with different medications. . . . It has also been demonstrated practical for the inner layer of the lining to be impregnated with antithrombotics and the outer with antiproliferatives and/or other medicational substances."); Fig. 4; col. 5:18-20 ("Fig. 4 is a view similar to that of Fig. 2 of an endoprosthesis with a multiple-layer lining and with its ends coated with medication,"); col. 5:34-41 ("The endoprosthesis . . . is completely enclosed in an inner lining component and an outer lining component."); Fig. 7; col. 6:30-44 ("The endoprosthesis 40 in the embodiment illustrated in Fig. 7 comprises a lining 42 and 43 in the form of a double walled sleeve. The outer lining component 43 of the in-place and expanded stent rests against the inner surface 46 of the blood vessel. Inner lining component 42 rests against the stent."); col. 7:16-35; col. 7:48-65; col. 8:19-10:19.

Lambert '246: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion.").

Bellamkonda '029: Fig. 6.

Dayton '382: Abstract ("The stent is then coated with a polymer or is formed from a polymer which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids . . ."); col. 4:4-10; col. 6:64-7:7; col. 8:18-19 ("a polymer forming the exterior surface of said stent for operative contact with said tissue . . .").

Burt '036: p.14:9-27; p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size.").

Goldin '568: Figs. 5A-5F; col. 9:7-12 ("... a substance that, when implanted in or juxtaposed against a living body . . ."); col. 22:46-23:3.

Palmaz '665: Col.3: 55-65 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into the body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded..."); col. 5:9-13; Figure 4; col. 8:9-14.

Palmaz '762: Col. 4: 14-19 (...expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway..."); col. 4: 53-56; col. 5: 43-45; col. 9: 1-6.

Palmaz '337: Col. 3:60-4:2 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into a body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded, whereby the intraluminal graft prevents the body passageway from collapsing and decreasing the size of the expanded lumen."); col. 4: 36-40; col. 5: 32-34; col. 7: 28-36; col. 8: 17-22.

Zaffaroni '254: Col. 7: 18-25 ("Secondly, the carrier contacts and bathes the inner surface of wall 11 for facilitating drug transfer from the carrier to the wall so that drug molecules can dissolve in a diffusive medium in the microporous wall and migrate through it to the outer surface thereof.").

Aebischer: Fig. 2A (disclosing one major surface facing the nerve stumps).

Dev: Abstract ("Polymer-coated stents could be used for local drug delivery to the vessel wall."); p. 273 ("... to compare these two drugs with respect to kinetics of their delivery to the arterial wall with the stent in place . . .").

Claim 15 [15D] (cont'd): the second major surface of the layer being adapted to be placed opposite to the damaged tissue,

Where Found in the Prior References:

Schwartz '823: Abstract ("The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen."); Figs. 6-9, 13, 15; col. 2:37-40 ("In essence, this improvement makes it possible to provide a stent able to support body lumens and conform to curves or irregularities in body lumens."); col. 2:44-54 ("The composite stent of the present invention can be delivered to the site of the occlusion by catheter and expanded conventionally, causing the film to expand or open radially along with the metallic elements of the stent and to be brought into contact with the body lumen. The polymeric film is flexible and preferably an elastic or stretchable film that is capable of conforming to the movement of the metallic stent elements when expanded into contact with a body lumen."); col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:48-54; col. 3:58-col. 4:6; col. 6:49-52 ("As shown in Fig. 13, the stent can be delivered to the body lumen and expanded (e.g. by use of a balloon catheter) into contact with the body lumen."); col. 6:33-37 ("As shown in Fig. 9, with the angioplasty procedure completed, balloon is deflated and withdrawn leaving stent firmly implanted within vessel with the film held in contact with the vessel."); col. 6:62-68 ("Once in the desired location, the stent can be released from the catheter and expanded into contact with the lumen as shown in Fig. 15 where it can conform to the curvature of the body lumen. The flexible film is able to form folds which allow the stent elements to readily adapt to the curvature of the body lumen.").

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14 ("The present invention satisfies this need by providing a separate sleeve to encompass the stent and serve as a local drug delivery device to prevent thrombosis."); col. 4:53-55 ("The present invention satisfies this need by providing a separate sleeve to encompass a stent to locally administer drugs to prevent restenosis."); col. 4:58-68 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. . . . Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 5:26-29; col. 6:49-55 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of

promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface"); col. 8:8-22; col. 8:58-60 ("The films were placed to line the circumference of a 2 cm length of ePTFE grafts, over which a 2 cm long stent was deployed."); col. 9:12-16 ("In addition, polymer-drug films which prevent thrombosis in the baboon and pig AV shunt system can be studied following stent-film placement in carotid, superficial femoral and coronary arteries following balloon injury of those vessels."); col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:12-20 ("Stents are typically implanted within a vessel in a contracted state and expanded when in place in the vessel in order to maintain patency of the vessel to allow fluid flow through the vessel. Ideally, the implantation of such stents is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:50-56 ("The stent can be used in coronary arteries or any other part of the vasculature or other body lumen where mechanical opening force is necessary or desirable to keep the vessel open or to maintain the stent flush against the lumen wall, and where an anti-restenosis, anti-proliferative or other types of therapeutic drug or agent is to be simultaneously positioned and diffused."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 2:23-33; col. 5:15-17; col. 7:56-62; col. 9:63-

67 ("The deployment of the stent can also be improved by . . . decreasing friction between the vessel or lumen wall and the stent."); col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:52-54 ("The invention provides prostheses which may be inserted into a lumen of a body and fixed to the lumen wall adjacent an area needing treatment."); col. 1:63-66 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery."); col. 2:7-9 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:25-27 ("The current invention contemplates the usage of any prosthesis which elutes drugs locally to treat a lumen in need of repair."); col. 6:36-38; col. 6:56-58 ("The stent shown in Figs. 2 and 4 is a metallic malleable design which may be forced against a lumen wall by a balloon catheter which fixes it into position."); col. 6:64-67 ("The variations of design shown in the embodiments of Figs. 1 and 2 show that the prosthesis of the invention must be secured against a lumen wall and must carry a drug-eluting polymer."); col. 9:67-10:3 ("By including a metal stent within the lumen of the polymeric prosthesis, the polymeric prosthesis is effectively held against the wall of the body lumen by the strength of the metal stent."); col. 10:23-38 ("The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen. This will bring the bioabsorbable element into supporting contact with a body lumen at an interior position of the body lumen to be treated and will position the bioabsorbable element to deliver drugs to the body lumen. Following the expansion of the stents into luminal contact, the balloon (if the expansion device is a balloon) can be deflated which allows the luminal flow to be restored."); col. 10:46-59; col. 11:10-13; col. 11:17-20; col. 11:50-53 ((b) a body including a plurality of support elements forming an open-ended, radially expandable, self-supporting tubular structuring having an interior surface and an exterior surface."); col. 12:1-15.

Berg '354: Page 2:14-18 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen. Examples of stents which have been successfully applied over a PTCA balloon and radially expanded at the same time as the balloon expansion of an affected artery include the stents disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) which are incorporated herein by reference in their entirety."); p. 2:34-36 ("Metal stents such as those disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) could be suitable for drug delivery in that they are capable of maintaining intimate contact between a substance applied to the outer surface of the stent and the tissues of the vessel to be treated."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting

polymeric surface on the stent."); p. 3:16-18 ("In operation, the stent made according to the present invention can deliver drugs to a body lumen by introducing the stent transluminally into a selected portion of the body lumen and radially expanding the stent into contact with the body lumen.").

Buscemi '450: Col. 3:14-15 ("The stent strengthens an area of the vessel that is in contact with the stent."); col. 3:21-25 ("The tubular main body includes an outer surface and inner surface. The outer surface of the main body faces an inner surface wall of the vessel. The inner surface of the stent faces a stream flowing through the lumen as shown in cross section in Fig. 2."); col. 4:61-64 ("The stent is secured by releasing the stent from compression so that the stent can radially spring out to abut against the inner surface wall of the vessel."); col. 6:49-52; col. 7:27-29; col. 8:9-11.

Ding '536: Col. 5:38-40 ("Surface material should minimize tissue rejection and tissue inflammation and permit encapsulation by tissue adjacent the stent implantation site.").

Dinh '227: Col. 1:32-35 ("The stent is typically inserted by catheter into a vascular lumen told [sic] expanded into contact with the diseased portion of the arterial wall, thereby providing mechanical support for the lumen."); col. 8:20-23 ("The term "stent" herein means any device which when placed into contact with a site in the wall of a lumen to be treated, will also place fibrin at the lumen wall and retain it at the lumen wall."); col. 8:37-43; col. 9:18-24 ("The stent is then delivered through the body lumen on the catheter to the treatment site where the stent is released from the catheter to allow it to expand into contact with the lumen wall.").

Domb '055: Abstract ("Preferred embodiments include catheters, tubes, and implants that abut tissue following implantation into the body . . ."); col. 4:25-32; col. 5:27-33; col. 5:49-54; col. 5:63-6:1 ("Coating that part of the tube, which is in contact with the mucosa, with the drug-loaded polymer provides a sustained release of steroids and antibiotics locally and at high concentration in the area which is critically affected, achieving the same effect as the systemic administration of the drugs without their side effects, throughout the duration of the intubation."); col. 6:8-18; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages.").

Kowligi '782: Abstract; col. 1:18-41; Figs. 2, 3; col. 10:18-67.

Hunter '981: Col. 4:24-38; col. 5:1-6; col. 16:31-56; col. 22:3-7; col. 22:54-58; col. 23:6-13 ("[M]ethods are provided for expanding the lumen of a body passageway, comprising inserting a stent into the passageway, the stent having a generally tubular structure, the surface of the structure being coated with an anti-angiogenic composition . . . such that the passageway is expanded."); col. 23:30-31; col. 23:46-51; col. 24:45-51; col. 24:66-25:5; col. 25:24-29; col. 25:48-54; col. 52:4-8 ("This film is designed to be placed on exposed tissue so that any encapsulated drug is released from the polymer over a long period of time at the tissue site."); 86:56-59; col. 87:11-22; col. 88:19-26.

Lambert '922: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion."); col. 3:54-61; col. 8:1-6.

Lambert '308: Page 3:24-27 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion.").

Myler '563: Col. 3:34-37 ("Stent 10 is illustrated in its expanded position at a treatment location adjacent vascular wall in an artery, in accordance with one aspect of the present invention."); col. 4:53-56 ("The exterior surface of the envelope which will contact the arterial wall is optionally made porous to enable the release of drugs from the envelope and/or stent to the treatment site."); col. 10:12-14 ("The balloon is inflated, thereby expanding the stent radially outwardly until it contacts either a previously dilated, or presently stenosed wall."); col. 10:56-61; col. 11:63-65 ("Once the stent has been positioned at the treatment site, axial elongating tension is released, and it is permitted to radially expand against the lumen wall."); col. 13:15-17 ("The exterior coating which will contact the arterial wall is optionally made porous to enable the release of drugs to the treatment site.").

Palmaz '417: col. 4:25-37 (" . . . expanding a portion of the catheter associated with the prostheses to force at least one of the prostheses radially outward into contact with the body passageway . . .").

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); Figs. 1 and 2; col. 9:18-10:3.

Strecker '746: Figs. 7 & 8.

Schiraldi '243: Col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-

soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Valentini '029: Abstract ("In particular, tubular channels which have a smooth inner surface and longitudinally oriented trabeculae result in significantly larger regenerated nerve cables and higher numbers of regenerated myelinated axons."); Figure 3; col. 2:32-35 ("Medical devices employing such selectively permeable materials, particularly semipermeable tubular devices having smooth inner skins, are disclosed for use in regenerating nerves."); col. 2:58-3:14; col. 5:33-41; col. 6:14-24.

Bawa '279: Col. 6:40-44; col. 12:29-34.

Wood '066: Col. 2:67-3:32 ("The object of this invention is to provide means for delivery effective dosages of therapeutic agents to sites of trauma such as wounds, thermal or chemical burns, ulcers, lesions, or surgical sites.").

Aebischer '486: Fig. 1.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:63-2:2; col. 2:21-32; col. 2:33-38; col. 2:39-46; col. 3:63-4:31 ("It can be of advantage for the lining to be of several layers, each impregnated with different medications. . . . It has also been demonstrated practical for the inner layer of the lining to be impregnated with antithrombotics and the outer with antiproliferatives and/or other medicational substances."); Fig. 4; col. 5:18-20 ("Fig. 4 is a view similar to that of Fig. 2 of an endoprosthesis with a multiple-layer lining and with its ends coated with medication."); col. 5:34-41 ("The endoprosthesis . . . is completely enclosed in an inner lining component and an outer lining component."); Fig. 7; col. 6:30-44 ("The endoprosthesis 40 in the embodiment illustrated in Fig. 7 comprises a lining 42 and 43 in the form of a double walled sleeve. The outer lining component 43 of the in-place and expanded stent rests against the inner surface 46 of the blood vessel. Inner lining component 42 rests against the stent."); col. 7:16-35; col. 7:48-65; col. 8:19-10:19.

Lambert '246: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion.").

Bellamkonda '029: Fig. 6.

Dayton '382: Abstract ("The stent is then coated with a polymer or is formed from a polymer which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids . . ."); col. 4:4-10; col. 6:64-7:7; col. 8:18-19 ("a polymer forming the exterior surface of said stent for operative contact with said tissue . . .").

Burt '036: p.14:9-27; p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size.").

Goldin '568: Figs. 5A-5F; col. 9:7-12 ("... a substance that, when implanted in or juxtaposed against a living body . . ."); col. 22:46-23:3.

Palmaz '665: Col.3: 55-65 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into the body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded..."); col. 5:9-13; Figure 4; col. 8:9-14.

Palmaz '762: Col. 4: 14-19 (...expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway..."); col. 4: 53-56; col. 5: 43-45; col. 9: 1-6.

Palmaz '337: Col. 3:60-4:2 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into a body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded, whereby the intraluminal graft prevents the body passageway from collapsing and decreasing the size of the expanded lumen."); col. 4: 36-40; col. 5: 32-34; col. 7: 28-36; col. 8: 17-22.

Zaffaroni '254: Col. 7: 18-25 ("Secondly, the carrier contacts and bathes the inner surface of wall 11 for facilitating drug transfer from the carrier to the wall so that drug molecules can dissolve in a diffusive medium in the microporous wall and migrate through it to the outer surface thereof.").

Aebischer: Fig. 2A (disclosing one major surface facing the nerve stumps).

Dev: Abstract ("Polymer-coated stents could be used for local drug delivery to the vessel wall."); p. 273 ("... to compare these two drugs with respect to kinetics of their delivery to the arterial wall with the stent in place . . .").

Claim 15 [15D] (cont'd): the layer having material release means for release of an at least one treating material in a unidirectional manner,

Where Found in the Prior References:

Peterson '166: Abstract ("A time-release chemical delivery system in which a bioactive compound is attached to a polymeric biodegradable carrier by a hydrolysable bond is disclosed. The bioactive compound can either be bound directly to the polymer or be attached to the polymer via a spacer group."); col. 1:28-38; col. 1:51-55 ("Another object of the instant invention is to provide a bioactive compound via covalent bonding to a polymeric backbone so that upon hydrolysis of said covalent bond said bioactive compound is released in active, unmodified form."); col. 1:60-62; col. 1:67-col. 2:2; col. 2:40-50 ("A further requirement of the polymeric carriers are that they contain a pendant group to which a reactive compound may be directly attached by a hydrolyzable bond or to which a spacer unit may be attached with the reactive compound attached to the spacer unit by a hydrolysable bond. Typically, the space [sic] unit will also be attached to the polymeric carrier by a hydrolyzable bond."); col. 2:51-60; col. 3:67-4:2; col. 4:3-7 ("The use of a spacer group may also provide desirable changes in drug release rate by allowing ease of hydrolysis of the drug."); col. 4:8-19; col. 4:56-5:2; col. 6:28-55; col. 6:55-62 ("Since the proximity of the reactive carboxyl group to the polymer backbone may interfere with the addition of a bioactive compound, especially a large molecule, and with the subsequent hydrolysis of a covalent bond formed by such condensation reaction, the use of a spacer group, preferably linear in nature, may be preferred in this invention."); col. 6:65-col.7:28 ("To be effective as hydrolysable carriers the polymers of this invention must have pendant reactive sites to which a bioactive compound may be attached. . . . These functional groups may react with functional groups of the bioactive compound to form a hydrolysable bond. The hydrolysable bond may be direct between the pendant group of the polymer and the reactive compound or it may be first reacted with a spacer unit which contains a similar reactive functional group. . . . The reactivity of the reactive sites is also affected by the distance of the reactive site from the backbone of the polymer."); col. 7:32-53 ("Spacer groups may be utilized in the practice of the instant invention to provide a hydrolysable unit which spaces the reactive compound further from the carrier backbone. As indicated hereinabove, the polymeric units may contain long pendant chains which place the reactive site on the pendant group further away from the carrier backbone. . . ."); col. 7:57-62 ("Bioactive compounds useful in this invention are those which contain a group which may react to form a bond with a pendant group or a spacer group. The bond is preferably hydrolysable and in particular are esters, including sulfates or phosphate esters, amides, carbonates and urethane bonds."); col.8:25-28 ("The reactive compound which is released over a period of time in the instant invention may be one which has a pharmacological affect upon the host, for example, a contraceptive drug in an animal."); col. 8:34-49 ("Factors which affect the release rate and the rate of absorption into the body of the host include . . . the composition of the polymer backbone, the length and character of the spacer groups and the character of the pendant groups The spacing of the bulky drug or chemically reacted compound from the polymer also affects the rate of release."); col. 11:25-12:4 (" . . . a bioactive compound chemically attached to said carrier by a hydrolysable bond, said bioactive compound containing a group which reacts with a group on the biodegradable polymer to form a hydrolysable bond and being effective in small dosages to produce a biological effect within said host upon release into the host by hydrolysis of the hydrolyzable bond."); col. 12:14-24 ("The chemical delivery system of claim 1 wherein said bioactive compound is indirectly coupled to said carrier by a hydrolyzable bond to a spacer compound. . . . The chemical delivery system of

claim 7 wherein said spacer compound is coupled to said bioactive compound by a hydrolyzable bond."); col. 12:28-30.

Schwartz '823: Col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:64-4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof."); col. 7:1-4 ("In yet another aspect of the present invention, various therapeutic substances can be incorporated in or applied to the polymeric film to provide such substances to the blood or to the lumen wall."); col. 7:14-25 ("Application of the therapeutic substance to the film can include applying it on the surface of the film or incorporating it into the film as it is made. For example, microcapsules can be used to carry the therapeutic substance either in or on the film and to provide timed-release of the substance to the blood, or to the blood vessel or both."); col. 7:25-34 ("Microcapsules containing one type of therapeutic substance could be provided on one side of the film and microcapsules containing another therapeutic substance could be incorporated on the other side of the film, thus providing a stent according to the present invention which provides one type of therapeutic substance (e.g. an anti-thrombotic drug) to the blood and another type of therapeutic substance (e.g. an antiproliferative drug) to the vessel wall."); col.8:5-11 ("The resulting stent has microcapsules containing one therapeutic substance on the inside (and able to contact blood once implanted in a blood vessel) and microcapsules containing a second therapeutic substance on the outside (and able to contact the vessel wall when implanted in contact with the vessel wall)."); col. 8:46-47.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14; col. 4:53-55; col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-33; col. 5:34-6:23 ("Many polymers can also be used to make the sheath, including biodegradable and non-degradable polymers. The polymer is selected depending on the drug selected, the polymer's compatibility with a subject and the ultimate pharmacologic effect desired. . . . Another alternative would be to use a polymer which is biodegradable over a short period of time. Naturally, the opposite characteristics would be selected for a desired prolonged release. The characteristics of the particular polymer for these purposes is well known to the skilled artisans

or can be determined by reference to standard references . . ."); col. 6:39-41 ("The initial prototype is a sleeve of polymer, either degradable or non-degradable, that covers the entire stent (Fig. 3)"); col. 6:64-68 ("The duration of drug delivery is accurately predicted by the characteristics of the polymer. For example, if the polymer is biodegradable, then the rate and duration of drug delivery is related to the thickness of the polymer."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface."); col. 8:23-54; col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33 ("In combination, a hollow tubular stent having a predetermined length and a separate sheath removably encompassing at least a portion of said hollow tubular stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug."); col. 11:11-12 ("14. The sheath of claim 1, wherein the polymer is biodegradable."); col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 5:4-9 ("The primary function of the

sheet of polymeric material is to deliver therapeutic agents or drugs to help prevent thrombosis and/or restenosis."); col. 5:49-6:25 ("The polymeric material is preferably bioabsorbable, and is preferably loaded or coated with a therapeutic agent or drug . . ."); col. 7:23-25; col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:63-2:6 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery. The prostheses may be completely biodegradable or may be bioabsorbable in whole or incorporated into the lumen wall as a result of tissue overgrowth, i.e. endothelialization. Alternatively, the prostheses may be biostable in which case the drug is diffused out from the biostable materials in which it is incorporated."); col. 2:28-30 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 2:55-58; Fig. 5; col. 6:5-10 ("When drugs are delivered locally via the prosthesis of the invention, they may be at therapeutic levels at the diseased site while at the lower limits of detectability in the bloodstream. So little drug is required for effective local treatment of a lumen that the drug may not be detectable in blood samples."); col. 6:36-38; col. 6:59-63 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously. the polymer may be biostable or bioabsorbable. If biostable, the drug would diffuse out of the polymer."); col. 6:64-67; col. 7:19-23; col. 7:53-55 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 7:59-8:25; col. 8:26-31 ("The compound which is preferred is a polyphosphate ester. Polyphosphate ester is a compound such as that disclosed in U.S. Pat. Nos. 5,176,907; 5,194,581; and 5,656,765 issued to Leong which are incorporated herein by reference. Similar to polyanhydrides, polyphosphate ester is being researched for the sole purpose of drug delivery."); col. 8:40-9:22 ("It is the hydrolytic instability of the phosphorous ester bond which makes this polymer attractive for controlled drug release applications. A wide range of controllable degradation rates can be obtained by adjusting the hydrophobicities of the backbones of the backbones of the polymers and yet assure biodegradability. The functional side groups allow for the chemical linkage of drug molecules to the polymer."); col. 12:12-15.

Berg '354: Page 2:27-31 ("Other methods of providing therapeutic substances to the vascular wall include simple heparin-coated metallic stents, whereby a heparin coating is ionically or covalently bonded to the stent. Still other methods of providing therapeutic substances to the vascular wall by means of stents have also been proposed such as in US-A-5102417 (Palmaz), WO-91/12779 "Intraluminal Drug Eluting Prosthesis" and WO-90/133332 "Stent With Sustained Drug Delivery".); p. 3:7-9; p. 3:22-23 ("It also provides a drug-containing stent which allows for a sustained release of the drug to vascular tissue."); p. 4:25-27 ("The ratio of therapeutic substance to polymer in the solution will depend on the efficacy of the polymer in securing the therapeutic substance onto the stent and the rate at which the coating is to release the therapeutic substance to the tissue of the blood vessel."); p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a

therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Abstract ("A stent made of biodegradable material includes a drug that is released at a rate controlled by the rate of degradation of the biodegradable material."); col. 1:61-63; col. 2:6-8 ("The mechanism of biodegradation is described as hydrolysis resulting in degradable products excreted in urine or reabsorbed into tissues."); col. 2:49-52 ("Also desired are stents which can deliver drugs or biologically active agents at a controlled rate to blood passing through the vessel lumen as well as to the vessel wall."); col. 2:56-61 ("The biodegradable stent is made from at least one biodegradable material that is also biocompatible and includes a drug which is released into the lumen of the vessel at a rate controlled by the rate of degradation of the biodegradable material."); col. 3:11-12 ("The rate of drug release is controlled by the rate of degradation of the biodegradable materials."); col. 3:53-55; col. 4:12-14; col. 4:23-25 ("The present invention further includes a main body having more than one biodegradable interior film layer."); col. 4:65-5:5 "In the most preferred embodiment, the biodegradable stent of the present invention is made of biodegradable materials that are also biocompatible. By biodegradable is meant that a material will undergo breakdown or decomposition into harmless compounds as part of a normal biological process"); col. 5:11-19 ("Suitable biodegradable materials for the main body of the stent of the present invention include polylactic acid, polyglycolic acid (PGA), collagen or other connective proteins or natural materials, polycaprolactone, hyaluric acid, adhesive proteins, co-polymers of these materials as well as composites and combinations thereof and combinations of other biodegradable polymers."); col. 5:21-37; col. 5:38-45 ("Consequently, the presence of different biodegradable materials in the stent permits the stent to degrade in a predictable, orchestrated fashion."); col. 5:46-54 ("As the stent biodegrades, drugs are administered to the surrounding tissue or to the blood stream. Thus, the rate of drug release is controlled by the rate of degradation of the biodegradable materials."); col. 6:3-8; col. 6:45-59; col. 7:2-9; col. 7:32-8:9; col. 8:27-30.

Ding '536: Abstract ("In one embodiment, the surface is provided with sites of high electronegativity species by coating with fluorosilicone which aid in controlled elution, particularly the initial release rate, and reduce thrombogenic activity."); col. 2:38-42 ("Such an approach is described by Winters, et al., in U.S. Pat. Nos. 5,182,317; 5,262,451 and 5,338,770 in which the amine functional groups of the active material are covalently bonded using a polyethylene oxide (PEO) on a siloxane surface."); col. 2:43-46 ("Another approach is described in U.S. Pat. No. 4,613,665 to Larm in which heparin is chemically covalently bound to impart a non-thrombogenic surface to the material."); col. 3:19-27 ("Accordingly, it is a primary object of the present invention to provide a coating and process for coating a stent to be used as a deployed stent prosthesis, the coating being capable of effective controlled long-term delivery of biologically active materials. Another object of the invention is to provide a coating and process for coating a stent prostheses using a biostable hydrophobic elastomer in which biologically active species are incorporated within a coating."); col. 6:16-27 ("The mechanism of incorporation of the biologically active species into the surface coating and egress mechanism depend both on the nature of the surface coating polymer and the material to be incorporated. The mechanism of release also depends on the mode of incorporation. The material may elute via interparticle paths or be administered via transport or diffusion through the encapsulating material itself."); col. 6:28-34; col. 6:35-48; col. 10:35-40 ("In addition, because of the negative

charges on the heparin itself, the electro-negativity of the fluorosilicone topcoat may be, at least in part, responsible for the modified heparin release kinetic profile."); col. 12:62-67 ("Whereas the polymer of the coating may be any biostable elastomeric material capable of being adhered to the stent material as a thin layer, hydrophobic materials are preferred because it has been found that the release of the biologically active species can generally be more predictably controlled with such materials. Preferred materials include silicone rubber elastomers and biostable polyurethanes specifically.").

Dinh '227: Col. 2:26-32; col. 3:10-14; col. 5:53-55 ("Suitable polymers could also be biodegradable polymers such as polyphosphate ester, polyhydroxybutyrate valerate, polyhydroxybutyrate-co-hydroxyvalerate and the like."); col. 6:13-22; col. 6:32-50; col. 6:50-56; col. 7:10-13 ("The adhesion of the coating and the rate at which the drug is delivered can be controlled by the selection of an appropriate bioabsorbable or biostable polymer and by the ratio of drug to polymer in the solution."); col. 7:13-23; col. 7:30-44; col. 7:45-51 ("The polymer used can be bioabsorbable or biostable polymer. Suitable bioabsorbable polymers include poly(L-lactic acid), poly(lactide-co-glycolide) and poly(hydroxybutyrate-co-valerate). Suitable biostable polymers include silicones, polyurethanes, polyesters, vinyl homopolymers and copolymers, acrylate homopolymers and copolymers, polyethers and cellulose."); col. 9:17-18; col. 12:38-50.

[Domb '055: Abstract ("Preferred polymeric coatings are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); col. 3:54-62 ("In the preferred embodiments, these have utilized bioerodible polymers as the matrix for the drug to be released, usually as a function of diffusion and erosion of the polymer. The advantage of these drug delivery systems is that they provide a sustained/continuous release of drugs locally and at a relatively high concentration in areas of the body, without systemic side-effects, throughout the duration of their release."); col. 4:11-13 ("It is a further object of the present invention to provide medical devices having prolonged low-dose, localized release of anti-microbial and anti-inflammatory agents."); col. 4:33-36; col. 5:27-33; col. 5:41-45 ("The drug-loaded polymer provides a sustained release of steroids and antibiotics locally and at a relatively high concentration in that area which is critically affected, without the side-effects of the systemic administration of the same drugs, throughout the duration of intubation."); col. 5:49-54; col. 5:60-6:1 ("An esophageal silicone stent coated with a film of polymer can be used to provide a site-specific controlled release of corticosteroids and antibiotics."); col. 6:3-7; col. 6:24-26 ("Examples of suitable polymers include ethylene vinyl acetate, polyurethane, silicones, hydrogels, polyurethane, and polyvinyl chloride."); col. 6:42-45 ("Release is a function of diffusion of the agent from the polymeric matrix, and varies by size, concentration and solubility of the agent, as well as by thickness and chemical composition of the polymeric matrix."); col. 7:10-20; col. 7:25-29; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 11:36-38 ("The medical device of claim 1, wherein the polymer is selected from the group

consisting of polyurethane, ethylene vinyl acetate, silicones, hydrogels, and polyvinyl chloride."); col. 11:39-44; col. 12:1-7; col. 12:11-22; col. 12:23-25; col. 12:26-31; col. 12:32-42.

Fox '096: Abstract ("A method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers, and antimicrobial agents . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 3:55-67 ("The polymeric coating agent component of the coating vehicle of the present invention is selected from the group consisting of biomedical polyurethanes, biomedical silicones, biodegradable polymers and combinations thereof."); col. 4:30-5:35; col. 7:22-25; col. 7:28-32; col. 11:34-48 ("Suitable biodegradable polymers include the homopolymers poly(glycolic acid), poly(D-lactic acid), poly(D,L-lactic acid), poly(D,L-ethyl-glycolic acid), poly(dimethylglycolic acid), poly(D,L-methylethylglycolic acid), and poly(E-caprolactone), as well as biodegradable polyhydroxy butyric acid and mixtures thereof. A preferred biodegradable polymer is polylactic acid (PLA)."); col. 11:51-56 ("The biodegradable polymer modulates the rate of release of antimicrobial drugs."); Table IV; col. 12:24-41 ("Suitable biomedical poly(lactic) polymers include the poly(L-lactide), poly(D-lactide) and the poly (D-L-lactic acid). . . . The poly(lactic acid) polymers are bioerodible, and while they can be used alone, it is preferred that they be combined with either a biomedical polyurethane or a biomedical silicone."); col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages."); col. 18:19-25; col. 20:54-58; col. 28:13-18; col. 29:38-40 (Adding a biodegradable material containing anti-microbial agents to the adhesive to provide controlled-release through degradation."); col. 36:21-31; col. 36:47-51; col. 36:65-37:7; col. 37:29-31; col. 37:56-57; col. 37:63-65; col. 37:66-38:9; col. 38:24-30; col. 39:39-41; col. 40:33-34; col. 40:39-42.

Hunter '981: Abstract; col. 3:42-61 ("A wide variety of molecules may be utilized within the scope of the present invention as anti-angiogenic factors, including for example Anti-Invasive Factor, retinoic acids and their derivatives, paclitaxel including analogues and derivatives thereof, Suramin, Tissue Inhibitor of Metalloproteinase-1, Tissue Inhibitor-1 and Plasminogen Activator Inhibitor-2, and lighter "d group" transition metals. Similarly, a wide variety of polymeric carriers may be utilized, representative examples of which include poly (ethylene-vinyl acetate) (40% cross-linked), poly (D,L-lactic acid) oligomers and polymers, poly (L-lactic acid) oligomers and polymers, poly(glycolic acid), copolymers of lactic acid and glycolic acid, poly(caprolactone), poly(valerolactone), poly(anhydrides), copolymers of poly(caprolactone) or poly(lactic acid) with polyethylene glycol, and blends thereof."); col. 5:27-32; col. 12:23-35 ("As noted above, the present invention provides compositions comprising an

anti-angiogenic factor, and a polymeric carrier."); col. 16:31-56 ("[A]nti-angiogenic compositions of the present invention are provided in a wide variety of polymeric carriers, including for example both biodegradable and non-biodegradable compositions. Representative examples of biodegradable compositions include albumin, gelatin, starch, cellulose, dextrans, polysaccharides, fibrinogen, poly (D,L lactide), poly (D,L-lactide-co-glycolide), poly (glycolide), poly (hydroxybutyrate), poly (alkylcarbonate) and poly (orthoesters) Representative examples of nondegradable polymers include EVA copolymers, siliconerubber and poly (methylmethacrylate). Particularly preferred polymeric carriers include poly (ethylene-vinyl acetate)(40% cross-linked), poly(D,L-lactic acid) oligomers and polymers, poly (L-lactic acid) oligomers and polymers, poly (glycolic acid), copolymers of lactic acid and glycolic acid, poly (caprolactone), poly (valerolactone), polyanhydrides, copolymers of poly (caprolactone) or poly (lactic acid) with polyethylene glycol and blends thereof."); col. 16:31-56; col. 16:66-17:6 ("Anti-angiogenic factors may be linked by occlusion in the matrices of the polymer, bound by covalent linkages, or encapsulated in microcapsules. Within certain preferred embodiments of the invention, anti-angiogenic compositions are provided in non-capsular formulations such as microspheres . . . pastes, threads of various size, films and sprays."); col. 17:7-26; col. 17:41-43 ("Anti-angiogenic compositions may also be prepared, given the disclosure provided herein, for a variety of other applications."); col. 18:15-49 ("Within further aspects of the present invention, polymeric carriers are provided which are adapted to contain and release a hydrophobic compound, the carrier containing the hydrophobic compound in combination with a carbohydrate, protein or polypeptide. Within certain embodiments, the polymeric carrier contains or comprises regions, pockets, or granules of one or more hydrophobic compounds."); col. 47:58-49:7; col. 56:45-57; col. 57:17-31; col. 59-65-60:48; col. 59: 32-59 ("Poly(e-caprolactone) is an aliphatic polyester which can be degraded by hydrolysis under physiological conditions and it is non-toxic and tissue compatible."); col. 69:19-62; col. 77:43-55 ("The release of paclitaxel, in this case, is dominated by polymer degradation."); col. 78:58-79:5 ("Although not specifically set forth above, a wide variety of other polymeric carriers may be manufactured, including for example . . ."); col. 84:62-86:24; col. 86:60-67.

Kinsella '608: Col. 11:18-24 ("Drug delivery systems that can be valuable include drug-impregnated polymer-coated metallic stents [and] biodegradable drug-eluting polymer stents . . .").

Kowligi '782: Col. 4:16-27 ("In regard to elastomeric coating 38 shown in Fig. 2, such elastomeric coating is selected to be a biocompatible elastomers and may be selected from the group consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 10:18-27; col. 10:28-32 ("The implantable vascular graft recited by claim 1 wherein said elastomers is selected from the group of elastomers consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 10:43-50; col. 10:60-67.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col.

1:46-55 ("Release of heparin from intravascular catheters in quantities sufficient to decrease thrombosis on the catheter has been achieved by either covalently bonding a charged molecule to a polymer or incorporating a large nonmobile charged molecule on the surface of the polymer . . ."); col. 1:62-65; col. 2:16-35; col. 2:40-50 ("In accordance with the present invention, there is provided a method for preparing a system suitable for localized delivery of biologically active compounds to a subject."); col. 2:55-67; col. 3:8-12; col. 3:29-49; col. 4:10-17; col. 7:29-32; col. 7:38-41; col. 8:62-9:19 ("Adventitia overlying the stent contained 360 times the concentration of forskolin in the blood and 305 times the concentration of forskolin in the contralateral artery. . . . In a similar model, etretinate, a retinoic acid analog, develops concentrations in the media of 250 ng/mg tissue at 24 hours. At 24 hours, this concentration was over 2000 times the concentration in the blood."); col. 9:31-37 ("These data demonstrate that a polyurethane coated nitinol stent is capable of delivering a lipophilic drug in high local concentration in the vessel wall. The large 450 fold differential of local tissue levels of forskolin over blood levels reflects the capability of this delivery system to provide high local concentration and potentially higher efficacy, with lower risk of systemic side effects."); col. 12:21-22 ("The method in accordance with claim 1, wherein the biologically active compound is a lipophilic compound."); col. 12:27-30 ("The method in accordance with claim 1, wherein the biologically active compound is a hydrophilic compound, said method further comprising linking the hydrophilic compound to a lipophilic carrier.").

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p. 2:10-19 ("Release of heparin from intravascular catheters in quantities sufficient to decrease thrombosis on the catheter has been achieved by either covalently bonding a charged molecule to a polymer or incorporating a large nonmobile charged molecule on the surface of the polymer . . ."); p. 2:25-30; p. 3:10-31 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); p. 4:2-12; p. 4:17-31; p. 15:25-16:14 ("Adventitia overlying the stent contained 360 times the concentration of forskolin in the blood and 305 times the concentration of forskolin in the contralateral artery. . . . In a similar model, etretinate, a retinoic acid analog, develops concentrations in the media of 250 ng/mg tissue at 24 hours. At 24 hours, this concentration was over 2000 times the concentration in the blood."); p.16:27-34 ("These data demonstrate that a polyurethane coated nitinol stent is capable of delivering a lipophilic drug in high local concentration in the vessel wall. The large 450 fold differential of local tissue levels of forskolin over blood levels reflects the capability of this delivery system to provide high local concentration and potentially higher efficacy, with lower risk of systemic side effects."); claim 14 ("The method in accordance with claim 1, wherein the biologically active compound is a lipophilic compound."); claim 16 ("The method in accordance with claim 1, wherein the biologically active compound is a hydrophilic compound, said method further comprising linking the hydrophilic compound to a lipophilic carrier."); claim 26.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8; p. 1:56-58.

Mitchell '711: Col. 6:24-28 ("Suitable solid carrier include, for example, calcium phosphate, magnesium stearate, talc, sugars, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, sodium carboxymethyl cellulose, polyvinylpyrrolidone, low melting waxes and ion exchange resins.").

Morris '781: Col. 10:50-54 ("Suitable solid carriers include, for example, calcium phosphate, magnesium stearate, talc, sugars, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, sodium carboxymethyl cellulose, polyvinylpyrrolidone, low melting waxes and ion exchange resins.").

Morris '182: Page 6:54-56 ("Suitable solid carriers include, for example, calcium phosphate, magnesium stearate, talc, sugars, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, sodium carboxymethyl cellulose, polyvinylpyrrolidone, low melting waxes and ion exchange resins.").

Myler '563: Col. 4:57-59; col. 4:60-67 ("[T]he stent can be provided with a solid drug carrier such as an impregnated porous solid wall or sponge for timed drug delivery."); col. 5:39-41 ("For the above reasons, even the expanded pores for drug delivery should be small enough to maximize or prevent cell penetration, but large enough for drug delivery."); col. 13:15-18 ("The exterior coating which will contact the arterial wall is optionally made porous to enable the release of drugs to the treatment site.").

Palmaz '417: Col. 11:8-11; col. 11:26-34 ("Examples of biologically compatible coatings would include coatings made of absorbable polymers such as those used to manufacture absorbable sutures. Such absorbable polymers include polyglycoides, polyacoides, and copolymers thereof. Such absorbable polymers could also contain various types of drugs, whereby as the coating is absorbed, or dissolves, the drug would be slowly released into the body passageway.").

Tice '330: Col. 3:20-33 ("A preferred group of polymeric wall forming materials includes those which are biodegradable such as aliphatic polyesters including polylactide, polyglycolide, polycaprolactone and copolymers thereof."); col. 8:38-51.

Thies '317: Abstract ("The capsules provide controlled release of the active agent over a prolonged period of time."); col.1:15-19 ("The art of encapsulation has developed various processes and methods for individually coating particular matter for purposes of controlled release or metering out of an active agent over a prolonged period."); col. 2:26-38; col. 2:43-47; col. 2: 48-51; col. 3:41-4:2; col. 6:35-39 ("Therefore, the presence of a soluble alkali metal silicate in the interior of the capsule causes much of the capsule coating material to simply disappear upon immersion in water thereby causing accelerated release of the active agent."); col. 7:36-11:68; col. 12:10-40; col. 13:4-14:3.

Tice '840: Col. 2:32-34; col. 2:38-55 ("The polymeric matrix material of the microparticles of the present invention must be a biocompatible and biodegradable polymeric material. . . . Suitable examples of polymeric matrix materials include poly (glycolic acid), poly-d,l-lactic acid, copolymers thereof, copolyoxalates, polycaprolactone, poly (lactic acid-caprolactone), and the like."); col. 2:56-3:8 ("The molecular weight of a polymer is also important from the point of view that molecular weight influences the biodegradation rate of the polymer. The drug can also be released from the microparticles as the polymeric excipient bioerodes. By an appropriate selection of polymeric materials a microparticle formulation can be made such that the resulting microparticles exhibit both diffusional release and biodegradation release properties."); col. 10:56-11:15; col. 12:6-9.

Tice '025: Col. 2:32-34; col. 2:38-55 ("The polymeric matrix material of the microparticles of the present invention must be a biocompatible and biodegradable polymeric material. . . . Suitable examples of polymeric matrix materials include poly (glycolic acid), poly-d,l-lactic acid, copolymers thereof, copolyoxalates, polycaprolactone, poly (lactic acid-caprolactone), and the like."); col. 2:56-3:8 ("The molecular weight of a polymer is also important from the point of view that molecular weight influences the biodegradation rate of the polymer. The drug can also be released from the microparticles as the polymeric excipient bioerodes. By an appropriate selection of polymeric materials a microparticle formulation can be made such that the resulting microparticles exhibit both diffusional release and biodegradation release properties."); col. 10:51-11:5; col. 12:1-4.

Lapka '244: Abstract; col. 2:35-63; col. 4:35-57 ("Among the bioabsorbable polymer materials suitable for use in the invention may be mentioned poly(lactic acid) or polylactic acid polymers, such as dl-poly(lactic acid) (or poly(dl-lactic acid)) polymers, poly-(glycolic acid) polymers, poly(hydroxybutyric acid) polymers and lactide/glycolid copolymers."); col. 4:58-5:5 ("The solid injectable drug material which constitutes the core material of the microcapsules may be any such injectable drug material for which it is desired to establish a long-acting, sustained release delivery system."); col. 32:5-16; col. 32:20-21; col. 32:28-34; col. 32:35-39 ("The process according to claim 8 wherein the core material is selected from the group consisting of cyclazocine, tetracycline, ehtisterone, digitoxin, antimony potassium tartrate, salmon calcitonin, ACTH, lypressin, sommatostatin, and insulin.").

Kent '189: Abstract; col. 1:12-28 ("The invention relates to a microcapsule composition comprising a core containing at least one water-soluble, hormonally active polypeptide and optionally a polymer hydrolysis modifying agent encapsulated in a biodegradable, biocompatible copolymer excipient. These compositions have sustained release characteristics. More specifically it relates to microcapsules wherein the core contains water-soluble polypeptides which are lutenizing hormone-releasing hormones, or mammalian growth hormones or polypeptides having thymosin-like activity and optionally an organic acid or its salts, or an acidic, neutral or basic inorganic salt which is capable of modifying the hydrolysis rate of the polymer excipient, encapsulated by a biocompatible, biodegradable excipient."); col. 1:50-58; col. 2:4-7 ("The encapsulating material may be a synthetic polymer comprising either poly(o-hydroxycarboxylic acids), poly(lactones), poly(acetals), poly(orthoesters) or poly(orthocarbonates)."); col. 11:5-38; col. 11:39-13:35 ("The number and type of encapsulating excipients which may be effectively used to practice this invention is limited only by the

requirements that the material be biocompatible and biodegradable. . . . Various combinations of alpha hydroxycarboxylic acids and certain lactones can be condensed to form such polymers, particularly lactic acid and glycolic acid or combinations thereof. . . . Similar biocompatible polymers based on glycolic acid and glycerol and the like are also known. . . . Several new biocompatible, biodegradable polymers derived from polyorthoesters and polyorthocarbonates also may be effectively used as encapsulating excipients in the practice of this invention. . . . There are also known polyacetals and polyorthoesters useful for this purpose . . ."); col. 17:42-18:67.

Tice '268: Abstract ("A compatible, biodegradable microcapsule delivery system for active ingredients, including hormonally active peptides, proteins, or other bioactive molecules . . ."); col. 1:32-46 ("More recently a polymer of poly(D,L-lactide-coglycolide) (DL-PLG), which is biodegradable and biocompatible with living tissue, has been used in microcapsules for longer acting delivery systems. Systems of microencapsulated active ingredients in polymers and copolymers have been used to achieve controlled release of chemical and biological pharmaceuticals."); col. 1:47-2:14 ("The microcapsule systems described in the above-publications all share a common feature in that the release of the compound is controlled by the porosity and/or erosion of a polymer continuum."); col. 2:45-53; col. 3:40-47 ("It should be noted, however, that other polymers besides poly(D,L-lactide-co-glycolide) may be used. Examples of such polymers include, but are not limited to: polyacetal polymers, polyorthoesters, polyesteramides, polycaprolactone and copolymers thereof, polycarbonates, polyhydroxybuterate and copolymers thereof, polymaleamides, copolyaxalates and polysaccharides."); col. 11:15-41.

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); col. 3:13-18; col. 3:34-38 ("In a preferred technique, one or more finishing coats of a second solution containing the same or another biocompatible polymer without the carrier is applied to provide an impermeable or substantially less permeable outer surface."); col. 4:29-34 ("In this embodiment, active factor 26 is incorporated within the membrane wall 12. The outer membrane surface 28 is nonporous, while porous inner membrane surface 22 allows for the diffusion therethrough of active factor 26."); col. 4:66-5:11 ("The membrane of the channel may be fabricated from any biocompatible polymers, such as, for example, polyethylene vinyl-acetate (EVA). . . . Preferable acrylates include methacrylates or hydroethylmethacrylates. The membrane instead may be composed of a bioresorbable biocompatible polymer, such as a polyanhydride, polyester, or mixtures thereof."); col. 5:18-28 ("In a preferred embodiment of the invention, the outer surface of the membrane is impermeable to solutes of any size, while the inner membrane surface contains pores [that] enable the active factors to diffuse out of the membrane and into the lumen of the channel."); col. 5:44-6:10; col. 6:17-22 ("The layering procedure allows deposition of an impermeable coat on the outer surface of the device, insuring that the active factors incorporated into the membrane walls will be inhibited from diffusing through the external surface, and will diffuse only through the inner membrane surface into the lumen of the channel."); col. 9:18-10:3; col. 10:10-12.

Folkman '560: Col. 1:56-2:23; col. 2:43-68; col. 3:18-23 ("The polymer matrixes, which are suitably used in the present invention, are biocompatible in the environment of use,

plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:36-51 ("Typical polymeric material suitable for forming the matrix . . . include . . . alkylene-vinyl acetate copolymers . . . crosslinked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:52-4:26 ("In the presently preferred embodiment the polymeric materials useful for forming the matrix are the ethylene vinyl ester copolymers of the general formula . . ."); col. 8:17-18; col. 11:56-12:20; col. 12:28-31; col. 12:36-43; col. 12:52-54 ("The therapeutic system for the administration of insulin according to claim 1, wherein the polymeric matrix is ethylene-vinyl acetate copolymer."); col. 12:59-61.

Cohen '496: Abstract; col. 2:46-66 ("In general, the invention features an improved method of making such a body, in which a biologically active material and the polymer below the glass transition temperature of the polymer and compressing the mixture above the glass transition point of the polymer. In preferred embodiments, the polymer is an ethylene-vinyl ester copolymer of the general formula . . ."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:65-4:39 ("In a presently preferred embodiment, the polymeric materials useful for forming the matrix are the ethylenevinyl ester copolymers of the general formula . . ."); col. 9:40-10:17; col. 10:18-32.

Schiraldi '243: Col. 1:58-60 ("Other polymers that might be added are vinyl copolymers, polysaccharides, gelatin and collagen."); col. 2:30-51; col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 3:14-34; col. 4:67-5:27; col. 10:3-7; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Helwing '868: Abstract ("The compositions may either be in capped form or leashed to a polymeric backbone. . . . The primary uses of the compositions are in controlled release applications such as drugs . . . or in any application where predictable hydrolytic release of the active agent is desirable."); col. 1:6-16 ("The present invention relates generally to compositions of matter and more particularly to covalently bonded compounds composed of active agents containing reactive functional groups The primary uses of the invention are in hydrolysable controlled release utilizations of active agents in such areas as pharmaceuticals, insecticides, herbicides, and the like."); col. 1:19-37 ("In addition . . . it may be highly desirable to have a system that permits the continuous controlled release of an agent . . ."); col. 1:38-2:11

("One of the most common methods of achieving predictable controlled release mechanism of an active chemical agent is to encapsulate the agent with another material which gradually degrades in the desired medium. . . . A similar method is to trap molecules of the active agent within a surrounding polymer matrix. The matrix structure is such that exposure to an environmental material, usually water, causes the matrix structure to gradually degrade until the surrounding matrix structure is decomposed to the extent that the active agent molecule is permitted to escape into the environment. . . . The Heller, et al. patent utilizes a polymer structure . . . subject to hydrolysis, that is, it is subject to degradation in a gradual manner upon contact with water."); col. 2:12-24 ("The usefulness of structures such as that taught in Heller, et al. patent is significantly dependent upon the unique bioerodable, or hydrolysable, bonding structure . . ."); col. 2:25-37 ("The bonds so formed between the ketene acetals or vinyl ethers and hydroxyl groups are readily hydrolysable under even mildly acidic conditions. It is postulated that similar results will be obtained between various other functional groups on active agents and ketene acetals or vinyl ethers, and that these linkages will be hydrolysable with degradation of the covalent bond in the presence of water providing an ideal mechanism for controlled release of chemical or biological agents."); col. 38-53 ("In the present invention, as active agents will be bonded directly to the controlled release matrix, specific structural design of the base component system will most directly affect control over the hydrophobicity of the overall matrix."); col. 2:55-3:27; col. 3:37-43 ("It is an object of the present invention to provide an aggregation of useful chemical compounds wherein a chemically active agent via its polar active (PA) functional groups is covalently bonded with a carbonium ion mechanism ("CIM") base group, the bond therebetween being hydrolysable in a predictable manner, resulting in controlled release."); col. 3:47-50; col. 3:62-66; col.3:67-4:17 ("The present invention is an aggregation of compositions consisting of a hydrolysable covalent bond formed between a base structure and an active agent structure. . . . The combinations are particularly adapted for use in controlled release of the active agents by way of hydrolysis. The usefulness of the combinations of the present invention is found in a wide degree of chemical and biological applications including drugs . . ."); col. 4:18-38 ("The inventive compositions of matter have the common property that the covalent bond joining the active agent to the base component is predictably hydrolyzable."); col. 4:39-5:6; col. 5:7-46; col. 5:47-50 ("An advantage of the present invention is that new compositions of matter may be created which are subject to predictable hydrolysis under selected environmental conditions."); col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20 ("Each of the compositions of the present invention has two distinct moieties joined by a hydrolyzable covalent bond. . . . The active component will have this chemical or biological effect when it is in its free molecular form but will not have the same effect when it is restricted in the inventive composition by the covalent bond. The hydrolytic decomposition of the covalent bond will act to release the agent so that it may again act in its original molecular form."); col. 7:21-8:50 ("Polymeric support substrates for the leashed systems would include polyvinyl alcohol, dextran, cellulose and similar polyhydroxy polymers."); col. 8:51-9:29 ("The common thread found in the various active agents is that each include one or more functional PA subgroups which are capable of forming the desired hydrolyzable covalent bond with the CIM subgroups of the base component in a predictable manner."); col. 9:30-52 ("With respect to other active agent functional PA groups and CIM base components, the bond structure will not be a pure orthoester linkage but will be of a similar hydrolyzable nature."); col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48 ("However, in the presence of water, the orthoester-type linkage is subject to hydrolysis as shown in equation EQ-2 and the Z group representing either the ketene

acetal or thioacetal."); col. 12:49-13:5 ("The hydrophobicity of the inventive compositions may be altered such that the composition hydrolyzes at different rates."); col. 19:57 ("As is clear from the above, the scope of possible compositions that can be created according to the present invention is extremely broad. . . . All of the inventive compositions are such that they may be created by the process of the present invention and all will be similar in that the CIM and PA groups will form a hydrolyzable covalent bond which will act to keep the inventive composition intact under environmental conditions until hydrolysis occurs."); col. 20:18-37 ("Timed-release drugs for controlled introduction into the blood stream or other body tissues or cavities are well known, including compositions referred to as pro-drugs. The inventive compositions are extremely well adapted for use in this field. . . . Along these lines, the inventive systems could be used to deliver not only general drugs, but cancer drugs, hormones, vitamins, fungicides and even used as a more durable sunscreen."); col. 20:46-54; col. 20:55-68 ("The preferred embodiment of the present invention may also be applied to a surface as a film of uniform consistency for use in several areas of application. . . . The chemically linked nature of the controlled release matrix affords not only the ability to apply such films, but permits the most compact physical structuring possible in a controlled release matrix as well as an assured even distribution of the desired agent."); col. 21:27-41; col. 21:42-46 ("The composition of claim 1 wherein said covalent bond is predictably degradable via hydrolysis such that the active agent component may be released in a controlled release manner under selected environmental conditions."); col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3 ("The composition of claim 1 wherein the covalent bond is destructible via hydrolysis at a predictable reaction rate in a specified environment to yield a hydrolytically degraded base component and the active component as separate molecules."); col. 23:4-col. 24:27.

Valentini '029: Col. 3:15-25 ("The semipermeable nerve guidance channels of the present invention can also be biodegradable.").

Greco '135: Abstract; col. 1:19-26 ("This invention relates to methodology for the surface modification of surgical implants permitting the binding of drugs which, after implantation, are slowly released. More particularly, this invention relates to improved surgical implants having sustained, localized delivery of pharmacological agents such as extended antibiotic activity or reduced thrombogenicity, and methods for producing same."); col. 1:29-2:59 ("The surface modification of surgical implants by the adhesion of pharmacological agents for the purpose of minimizing infection and prosthesis rejection is well-known and has generated broad interest for some time. . . . The present Application is therefore an effort to further disclose and particularize this aspect of the invention, i.e., the development of the antibiotic bonded prosthesis utilizing an anionic surfactant and the oppositely charged drug, antibiotic or other agent or factor."); col. 3:8-19 ("An object of the present invention is to provide improved surfactant-modified implantable devices having a drug, including antibiotics, antithrombogenic agents, thrombolytic agents, disinfectants, etc., bound to the surface thereof. . . . Another object of the present invention is to provide an improved implantable device having a drug bound thereto of improved release times."); col. 3:22-27; col. 3:30-43; col. 4:2-39; col. 5:30-6:58 (disclosing process by which antibodies can be bound to thermoplastic substrates); col. 7:46-9:3; col. 9:10-12.

Bawa '279: Abstract; col. 1:16-36; col. 2:27-35 ("With the foregoing and other objects in view, the invention herein provides a sustained-release polymeric hydrogel dosage form useful for topical, systemic or transdermal administration of a medicinal agent comprising one or more polymerizable hydrophilic polymers, an ion-exchange resin, a cross-linking agent and optionally one or more hydrophobic polymers."); col. 2:39-46; col. 2:47-68 ("The preferred hydrophilic monomers are the hydroxyalkyl esters, specifically hydroxyethyl methacrylate (HEMA)."); col. 4:14-25; col. 6:40-44 ("The invention contemplates a variety of processes for preparing the sustained-release polymeric hydrogel dosage form whereby the medicinal agent is retained by the polymeric matrix and, upon tissue contact, is gradually released into the tissue."); col. 7:15-21; col. 8:1-6; col. 8:29-49; col. 8:54-55; col. 8:66-68; col. 11:42-54; col. 13:10-17; col. 13:26-14:14.

Aebischer '627: Col. 3:23-49 ("In addition, these polymeric materials have the capacity for sustained release of the embedded substance at a controlled rate."); col. 3:57-4:3 ("The polymeric insert includes pores having a molecular weight exclusion of from about 1 kD to about 1,000 kD, but preferably from about 25kD to about 100 kD. In one preferred embodiment, the polymeric insert includes a hydrophobic matrix such as ethylene-vinyl acetate copolymer."); col. 6:52-59 ("the insert may be composed of any biocompatible material having the desired pore size and being composed of materials which do not limit the activity of the substance embedded therein. . . . [H]ydrophobic matrices such as ethylene vinyl acetate are particularly useful."); col. 7:3-12 ("One way of providing the source of neurotransmitter include incorporating it into the polymeric insert. The encapsulating material provides a protective environment for substances such as neurotransmitters or cell growth factors embedded therein, while affording sustained release of the substance at a controlled rate therefrom."); col. 7:13-28; col. 7:29-56 ("The release rate may also be controlled by the amount of pure, impermeably polymeric material coating the effector substance-embedded insert; the more (or thicker the) coatings, the slower the release rate. Materials such as polyurethane or pure ethylene-vinyl acetate are particularly useful for this purpose."); col. 10:31-34 ("To retard dopamine release, three coats of 10% EVAc were applied to each rod by repeated immersion . . ."); col. 14:29-32; col. 14:45-49; col. 14:57-58.

Wood '066: Abstract ("A controlled-release bandage containing therapeutic agents in a poly(vinyl alcohol) cryogel is disclosed. The bandage may include . . . hydrophobic particles to further insure controlled and constant release of therapeutic agents."); col. 2:56-66 ("Bandages comprising cryogel and therapeutic agents are used to provide a protective covering and to provide a controlled and uniform administration of therapeutic agents to sites of trauma such as wound, thermal or chemical burns, ulcers, lesions or surgical sites. Cryogel bandages may include . . . particles having hydrophobic properties, which absorb the therapeutic agent and release it in an uniform and controlled manner."); col. 3:47-4:36; col. 7:6-32 ("The release of therapeutic agents from the bandage has been found to be further controllable by including insoluble particles capable of adsorbing or forming salts with the therapeutic agent in the bandage. . . . Other examples of suitable insoluble particles include hydrophobic resins, silica, hydroxyl apatite and aluminum oxide."); col. 7:43-50; col. 8:55-56; col. 26:8-18 ("The bandage of claim 1 wherein the insoluble particles capable of adsorbing or forming salts with the therapeutic agent are a hydrophobic resin particles.").

Strecker '746: Abstract; col. 1:63-2:2; col. 2:21-32; col. 3:5-17 ("Another sensible advanced version is characterized in that medications in the lining are dissolved in the wrapping material or included in the form of beads."), ("It can be practical for there to be more or less openings in the wall of the lining next to the lumen than there are in the wall next to the inner surface of the vessel. The ratio can be exploited to prescribe the dosage of medication to the lumen or wall of the blood vessel."); col. 3:17-26 ("The wrapping material can also to advantage be biodegradable When the material is biodegradable, the medication will be released not by diffusing out of the vehicle but by escaping as the vehicle that the medication is dissolved in or that accommodates the beads that encapsulate the medication at its surface decomposes and by accordingly coming into contact with body fluids."); col. 3:27-33; col. 5:10-12; col. 5:38-41; col. 6:1-17; col. 6:35-38; col. 7:16-37 ("a lining impregnated with medication for delivery to a wall of said body lumen"); col. 7:48-65; col. 8:19-10:19; Figs. 7 & 8.

Lambert '246: Abstract ("The biologically active compound is, therefore, released only at the site where it is desired, i.e., where the prosthetic article is positioned."); col. 1:46-55 ("Release of heparin from intravascular catheters in quantities sufficient to decrease thrombosis on the catheter has been achieved by either covalently bonding a charged molecule to a polymer or incorporating a large nonmobile charged molecule on the surface of the polymer . . ."); col. 1:57-61; col. 2:15-34 ("Increasing the lipid solubility of the compound slows release from the polyurethane, and increases the tissue retention. More lipid soluble compounds are, therefore, preferred agents for use in the practice of the present invention."); col. 2:38-40 ("In accordance with the present invention, there is provided a method for preparing a system suitable for localized delivery of biologically active compounds to a subject."); col. 2:40-49; col. 2:53-65; col. 7:31-33 ("The results of this example demonstrate that polyurethane stent coatings can concentrate and release lipophilic drugs in vitro."); col. 8:58-9:4 ("Adventitia overlying the stent contained 360 times the concentration of forskolin in the blood and 305 times the concentration of forskolin in the contralateral artery. . . . In a similar model, etretinate, a retinoic acid analog, develops concentrations in the media of 250 ng/mg tissue at 24 hours. At 24 hours, this concentration was over 2000 times the concentration in the blood."); col. 9:31-37 ("These data demonstrate that a polyurethane coated nitinol stent is capable of delivering a lipophilic drug in high local concentration in the vessel wall. The large 450 fold differential of local tissue levels of forskolin over blood levels reflects the capability of this delivery system to provide high local concentration and potentially higher efficacy, with lower risk of systemic side effects."); col. 10:47-50; col. 10:62-64 ("The drug delivery system of claim 1 wherein the biological agent is absorbed substantially throughout the entire thickness of the polyurethane elastomer coating."); col. 11:16-17 ("The drug delivery system of claim 8, wherein said biologically active compound is a lipophilic compound."); col. 11:30-31; col. 11:36-40; col. 12:12-13; col. 12:17-21; col. 12:53-54.

Bellamkonda '029: Col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 5:32-48 ("The agarose hydrogels of this invention may be used as a carrier to present various ECM proteins or peptides We prefer covalent

immobilization of ECM proteins to the hydrogel backbone."); col. 7:26-32 ("In a preferred embodiment, laminin-derived oligopeptidic fragments . . . are coupled to the hydroxyl backbone of agarose, using any suitable method."); col. 9:36-48 ("These growth factors may be incorporated into the channel membrane . . ."); col. 11:7-8 ("Additionally, the membrane may be composed of a biodegradable material."); col. 11:41-50; col. 12:13-16 ("Preferably the permselective membrane is fabricated to be impermeable to some of these substances so that they are retained in the proximity of the regenerating nerve ends."); col. 12:42-49; col. 12:50-56; col. 15:67-16:17; col. 23:54-24:55.

Dayton '382: Abstract ("The stent is then coated with a polymer . . . which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids, with the equilibrium being controlled by charge distribution, concentration and molecular weight of the bioactive substance in relation to the pore size of the polymeric carrier for controlled prolonged release of said bioactive substance."); col. 1:9-17 ("The present invention relates to an improved percutaneously inserted endoprosthesis device which is permanently or temporarily implanted within a body vessel, typically a blood vessel. More particularly, the present invention relates to a new procedure for administering localized bioactive substances via prosthesis designs . . ."); col. 3:36-39; col. 3:62-4:17 ("Among these polymers are polymers having a microporous structure, such as . . . biodegradable polylactic acid polymers, polyglycolic acid polymers . . ."); col. 4:24-33 ("A bioactive substance is preferably admixed in the polymer for elution from the microporous structure of the stent or coating on the stent after implantation. The rate of elution of the bioactive substance is controlled by selecting a pore size for microporous structure . . ."); col. 6:64-7:7 ("Also included in the polymer is a bioactive substance having a charge distribution, concentration and molecular weight selected which achieves an equilibrium in relation to the pore size of the polymeric carrier with said surrounding body tissues or fluids."); col. 7:8-14; col. 7:20-23.

Burt '036: p.4:19-33 ("Within one aspect of the present invention, compositions are provided . . . comprising (a) an anti-angiogenic factor and (b) a polymeric carrier. A wide variety of molecules may be utilized within the scope of the present invention as anti-angiogenic factors Similarly a wide variety of polymeric carriers may be utilized, representative examples of which include poly(ethylene-vinyl acetate) . . . and copolymers of polylactic acid and polycaprolactone."); p.10:17-25; p.14:9-27; p.21:2-4; p.51:1-52:35.

Goldin '568: Abstract; col. 1:21-34 ("In certain circumstances, another desirable use of controlled release methods is to target the delivery of a therapeutic agent specifically to the tissue or site that can benefit from the presence of such an agent."); col. 1:35-41 ("Several classes of controlled release strategies have been developed, principally involving: (a) release by controlled diffusion; . . . and (c) release limited by chemical control of the interaction of the agent with a substrate to which it is adsorbed or bound."); col. 1:43-62 ("Release by controlled diffusion may be accomplished by means of containment of the therapeutic agent within a substrate whose small pore size and/or tortuosity of diffusion path thereof limits the diffusion of said agent through the substrate. . . . The therapeutic agent can be incorporated within the diffusion-limiting substrate Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:8-16 ("Towards that end, diffusion-controlled slow release devices have

been fabricated from biodegradable polymers . . ."); col. 2:24-28; col. 3:42-53 ("Release by chemical control most commonly involves chemical cleavage from a substrate to which a therapeutic agent is immobilized, and/or by biodegradation of the polymer to which the agent is immobilized."); col. 3:54-65 ("Another variant of release by chemical control termed herein "controlled noncovalent dissociation or 'CND'", relates to release resulting from dissociation of an agent that is bound temporarily by non-covalent binding of the agent to a substrate."); col. 4:25-45 ("The microskin is specifically tailored to bind macromolecules . . . noncovalently by cooperative secondary bonds, and slowly release the macromolecules by controlled non-covalent dissociation (CND)"); col. 4:63-66; col. 6:1-19 ("Because preferred embodiments of the CND controlled Release Device and methods of use thereof employ membranes whose pore size is normally much greater than molecular dimensions, the kinetics of release are governed primarily by the strength and number of the reversible cooperative secondary bonds which immobilize said protein for CND."); col. 6:20-29 ("Limitation of the toxicity associated with the macromolecules to be released results from selective delivery to the site of action in the amounts and at the time needed. While in practice, the temporal and spatial selectivity of the current invention may not be absolute, it is clearly an improvement over more conventional modes of delivery . . ."); Fig. 1A; Fig. 1B; col. 8:65-9:6; col. 9:18-22; col. 9:23-30; col. 9:43-50 (" . . . delivery from controlled release devices can be controlled by diffusion out of said device, dissociation of chemical bonds, and the like."); col. 9:51-55; col. 10:45-54; col. 17:40-54 ("[S]ynthetic polymers . . . may be derivatized to attach functional groups which may react under appropriate circumstances to form covalent bonds with the macromolecules one wishes to bind and release in a controlled manner."); col. 20:9-12 ("By appropriate use of said Device, one can selectively target a therapeutic site . . ."); col. 20:46-21:19 ("[W]hen the pore size of the underlayment and/or the microskin approaches submicron dimensions and/or the thickness of said Devices approaches millimeter dimensions or greater, diffusion of the agent to be delivered out of said device may contribute to or even be the predominant process governing controlled release from said Device."); col. 21:47-49 ("A coating of a permeable guide tube, with a secondary membrane designed to exclude macromolecules from without."); col. 27:10-18; col. 32:26-31.

Palmaz '762: Col. 10: 28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '337: Col. 9: 24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Zaffaroni '254: col. 2:6-9 ("Still another approach has been to enclose the drug within a single capsule having a polymeric wall or walls through which the drug can pass, for example, by diffusion."); col. 2:16-26 ("Additionally, these prior art devices have generally been based on the use of a single material, such as silicone rubber polymers, especially polydimethylsiloxane, as the diffusion control membrane. In large part, these polymers were selected because of their permeability to some important drug molecules. But, it has been found that mere high permeability without consideration of release rate controlling properties can be a significant

disadvantage which defeats the primary object of an acceptable drug delivery device."); col. 4:54-58 ("In operation, solid drug carrier 13 serves as a reservoir 12 by supplying dissolved drug 14 to the micropores 15 of wall 11 as drug molecules move through the carrier to bathe the inner surface of wall 11."); col. 7:18-25.

Langer I: p.29 ("In the bioerodible system, the drug is distributed relatively uniformly throughout the plastic as in matrix systems, but it differs from the matrix in that its plastic portion decreases with time. As the plastic surrounding the drug is eroded, the drug escapes. . . . The most popular bioerodible polymers have been absorbable suture materials such as polylactic acid."); p.29-30 ("The second type of chemically controlled system is known as a pendant chain system. In simplest form, the drug is attached via chemical bonds to a polymer backbone. It could also be attached via a spacer group Release occurs when water reacts to break those bonds, thereby freeing the drug. Release rates are adjusted by varying the hydrophilicity of the polymer backbone. Systems could also be designed so that an enzymatic reaction could break the drug-polymer bonds."); p.29 Figure legend ("Chemically controlled pendant chain drug-delivery system. Here, the drug is bound to a polymer backbone and released by hyd[r]olytic or enzymatic cleavage, the key to controlling the medication's delivery.").

Langer II: p.217-18 ("In chemically controlled systems, release is accomplished either by biodegradation of the polymer . . . or by chemical cleavage of the drug from a polymer backbone to which the drug had been bound as a pendent group."); p.218 Fig. 3; p.219 Fig. 4 ("Chemically controlled pendent-chain drug-delivery system. Here, the drug is bound to a polymer backbone and released by hydrolytic or enzymatic cleavage."); p.221-225 ("Contraception" "Immunization" "Anticoagulation" "Cancer" "Insulin Delivery" "Controlled-release formulations may be applied to other clinical areas, including the release of narcotic antagonists, antibiotics, interferons, anesthetics, anti-arrhythmics, and antimalarial drugs.").

Langer III: p.25 ("Matrix Systems"); p.26-27 ("From a chemical standpoint, Heller has considered bioerodible systems in terms of three dissolution mechanisms: [1] water-soluble polymers insolubilized by degradable cross-links; [2] water-insoluble polymers solubilized by hydrolysis, ionization, or protonation of pendant side-groups; and [3] water-soluble molecules. These mechanisms represent extreme cases, and erosion by a combination of mechanisms is possible."); Fig. 3-3; Fig. 3-4; p.27-28 ("In pendant chain systems, a drug is chemically bound to a polymer backbone-chain and is released by hydrolytic or enzymatic cleavage. . . . The polymer system can be either soluble or insoluble . . . insoluble forms are more desirable for long-term controlled-release implants. The backbone may also be biodegradable or nonbiodegradable. . . . The drug itself can be attached directly to the polymer or attached via a spacer group. The spacer group may be used to affect the rate of release and hydrophilicity of the system.").

Langer & Peppas: Fig. 5; p.80-83 ("Matrix Systems"); p.83 ("Polymers for Diffusion-Controlled Systems"); p.84; p.85 ("Ethylene-vinyl acetate (EVA) copolymers have found major applications in controlled release of bioactive agents because of their relatively good chemical stability, biocompatibility, and inertness."); Fig. 7; p.86-87 ("Chemically controlled drug release generally involves one of two types of systems: 1) Erodible systems in which the drug is dispersed in a biodegradable polymer and drug release is influenced by the rate of degradation of the polymeric material, and 2) pendant chain systems in which the drug is attached to a polymer

through a hydrolytically or enzymatically labile linkage. Drug release is influenced by the rate of degradation of this linkage."); Fig. 8; p.87-100 (describing and identifying polymers for biodegradable drug release systems); p.100-101 ("In [pendant chain systems] a drug is chemically bound to a polymer backbone and is released by hydrolytic or enzymatic cleavage. . . . [I]nsoluble [backbones] are more desirable for long-term controlled-release implants. . . . The drug itself can be attached directly to the polymer or it can be attached via a spacer group. The spacer group may be used to affect the rate of release and hydrophilicity of the system. To achieve near constant release, the cleavage of the drug from the polymer must be the rate-limiting step. . . . There has recently been interest in developing controlled-release systems using pendant chain polymers for clinical applications."); p.114-16 ("Medical applications of controlled-release systems can be divided into four general areas: oral systems, transdermal systems, external implants, and subcutaneous implants.").

Langer IV: p.36 ("In matrix systems, the drug is uniformly distributed through a polymer."); Fig. 2; p.37 ("Two systems of chemical control exist. The first mechanism is bioerosion or biodegradation of the polymer. As the polymer surrounding the drug is eroded, the drug escapes. . . . The second type of chemically controlled system is known as a pendant chain system. In simplest form, the drug is attached via chemical bonds to a polymer backbone. It could also be attached via a spacer group. Release rates are adjusted by varying the hydrophilicity of the polymer backbone. Systems could also be designed so that an enzymatic reaction could break the drug-polymer bonds."); p.37 Fig. 3 ("Idealized diagram of the cross-section of a cylindrical or spherical bioerodible matrix."); p.37 Fig. 4 ("Idealized diagram of a chemically controlled pendant chain drug delivery system. The drug could be connected to the polymer backbone as shown or could be coupled to a spacer group attached to the polymer backbone."); p.41-42 ("The second type of [contraceptive] system is a subdermal implant composed of a biodegradable polymer."); p.44 ("Small (0.3 mm³) injectable pellets of ethylene-vinyl acetate copolymer containing 100 ug of a test antigen, bovine serum albumin, were positioned subcutaneously in mice.").

Langer V: p.24 (" Examples of polymers with these properties include nondegradable polymers such as ethylene-vinyl acetate copolymers (EVAc), and biodegradable polymers such as polylactic or polyglycolic acid.") ("Theoretically, the [biodegradable] polymers should have a hydrophobic backbone, but with water-labile linkage.").

Langer VI: p.115 (One approach that has received increasing attention as a means of prolonging drug release has been the incorporation of drugs in solid polymers (e.g., silicone rubber, ethylene-vinylacetate copolymer). This method permits drugs to be released for long time periods in a controlled fashion."); p.120-124 ("The ideal [biodegradable] polymer would have a hydrophobic backbone, but with water labile linkage.").

Laurencin & Langer: Fig. 2; p.304-306 ("Matrix Systems"); p.306-307 ("Three dissolution mechanisms for bioerodible polymeric devices are found in general: Type 1: water soluble polymers that are made insoluble through crosslinks that are degradable. On exposure to an aqueous environment, crosslinks are broken, polymer dissolves, and release occurs. Type 2: water insoluble polymers that on exposure to an aqueous environment are solubilized by hydrolysis, ionization, or protonation of pendant side groups. Type 3: water insoluble polymers

containing hydrolytically unstable backbone linkages. On exposure to an aqueous environment, polymer chains are cleaved to small water soluble monomers."); p.307 Fig. 4; p.308-309 ("In [pendant chain systems], drug is chemically bound to the backbone of a polymer. Release takes place by hydrolytic or enzymatic cleavage. . . . Polymer systems can be soluble or insoluble, and the backbone itself may be bioerodible or nonbioerodible. Soluble backbone chains are generally used for transport functions such as cell targeting; insoluble forms are more desirable for long-term controlled release implants. Drug can be chemically attached to the polymer directly or through a spacer group. The spacer group may be used to affect the rate of release or hydrophilicity of the system."); p.308 Fig. 5 ("Chemically controlled pendant chain drug delivery device. Drug bound to polymer backbone is released by hydrolytic or enzymatic cleavage."); p.313-316 (clinical applications of EVAc and biodegradable polymers).

Langer VII: p.1529 ("Chemical control is accomplished either by polymer degradation or chemical cleavage of the drug from a polymer."); p.1529 Fig.1(B), (C) and (D); p.1530 ("Examples of polymers that perform in this way are non-degradable ethylene-vinyl acetate copolymer and degradable lactic acid-glycolic acid copolymers."); p.1531-32 ("Theoretically, the [ideal surface-eroding] polymer should be hydrophobic but should have water-labile linkages.").

Langer & Moses: p.341-42 ("[W]e proposed that an ideal polymer would have a hydrophobic backbone, but with a water labile linkage."); p.342-44 ("One such report . . . employed the porous ethylene-vinyl acetate copolymer (EVAc) system to provide sustained release of fibroblast growth factor (FGF) or epidermal growth factor (EGF).").

Chien: p.32-33 ("[The hydrolysis-activated] controlled drug delivery system depends on the hydrolysis process to activate the release of drug molecules. . . . The release of a drug from the polymer matrix is activated by the hydrolysis-induced degradation of polymer chains and controlled by the rate of polymer degradation.") ("[The enzyme-activated] controlled drug delivery system depends on the enzymatic process to activate the release of drug. . . . The release of drugs is activated by the enzymatic hydrolysis of the biopolymers by a specific enzyme in the target tissue."); p.37 ("An ideal site-targeting drug delivery system has been proposed . . . constructed from a nonimmunogenic and biodegradable polymer backbone having . . . a drug moiety that is covalently [sic] bonded to the polymer backbone through a spacer and contains a cleavable [sic] group that can be cleaved only by a specific enzyme(s) at the target tissue.").

Thomson: p.34-36 ("The degradation of synthetic polymers is, in general, brought about by simple hydrolysis, although in some cases enzymatic processes assist in the degradation mechanism.").

Hanes & Langer: p. 647 ("Polymers can also be used to deliver vaccines in a controlled manner."); p.648 ("Biodegradable polymeric devices or pendant chain systems are examples of chemically controlled devices. In the former, molecules are typically dissolved or entrapped in a biodegradable, bioresorbable polymer matrix As the polymer degrades and erodes, molecules are released to the surroundings. In pendant chain systems, molecules are chemically attached to the backbone of a polymeric carrier using hydrolytically or enzymatically degradable bonds. In this case, the molecules are liberated as the bonds holding them to the polymer are

cleaved."); p.649 Fig. 29.2; p. 652 ("For the present development of vaccine delivery systems, the use of biodegradable polymers presents significant advantages over the use of nondegradable systems."); p.654-55 ("There are many such polymers that may prove useful for controlled delivery of vaccines; however, no degradable polymer systems has been more widely studied with respect to release kinetics than the lactide/glycolide polyesters."); p.655-56; p.656-58 ("Advantages of Controlled Release for Immunization").

Batz: p.26-27 ("Based on their chemical structure polymeric drugs are divided into the following three groups . . . b) Drugs in which the active substance of known biological activity is bound to a polymeric carrier molecule via a functional group."); p.36-43 ("Polymeric drugs formed by covalent bond of known active components to soluble macromolecular carriers"); p.48 ("Polymeric Forms of Deposit Without Covalent Bond Between Drugs and Polymeric Materials.").

Donaruma: p.10 ("Allan, Chopra, Neogi, and Wilkins, in studies concerned with the design and synthesis of controlled release pesticide polymer combinations, investigated the duration of effectiveness of various herbicidal phenoxyacetic acids chemically bound as pendant substitutes to natural or synthetic water-soluble and water-insoluble polymers."); p.17, 19-20 ("[I]t can be seen that in some cases portions of the polymer repeat unit are structurally constituted so that by hydrolysis the polymer chain or a pendant group may be sundered by hydrolysis. . . . Chemically combining a drug in a polymer may offer a means of sustained release and/or prolonged activity of drugs and/or drug latention. These are not new concepts, and examples are reported in the literature.").

Harris I: p.334 ("As reported in this review, our work has involved the syntheses and evaluation of polymers containing pendant aquatic herbicides."); p.344 ("The herbicide release rates of polymers containing herbicides as pendant substituents are extremely slow in water with pH=C at 30°C. The herbicide release rates, however, can be increased by incorporating hydrophilic groups along the polymers' backbones").

Feld: p.113-15 ("One approach to obtaining these formulations has been the synthesis of polymers that contain pesticides as pendent side chains. . . . Pesticide release occurs by the slow, sequential hydrolysis of the pesticide-polymer chemical bonds. This provides a sustained release of the pesticide over an extended period of time. The actual release depends on the nature of the pesticide polymer bond and the dimensions and structure of the resultant macromolecular combination."); p.116-17 ("It was postulated that increasing the length of the pendent side chain would enhance the hydrolysis of the herbicide-polymer bond."); 117-19 ("Herbicide reactivation was produced enzymatically using lipase, acetylcholinesterase and trypsin.").

Harris & Post I: p.622 ("One approach to obtaining controlled-release pesticide formulations that contain a high percentage of pesticide has been the synthesis of polymers that contain pesticides as pendent side chains. The pesticide is presumably released by the slow sequential hydrolysis of the pesticide-polymer chemical bonds. . . . It was postulated that increasing the length of the pendent side chain would enhance the hydrolysis of the herbicide-polymer bond.").

Harris & Post II: p.225 ("One approach to obtaining controlled-release pesticide formulations that contain a high percentage of pesticide has been the synthesis of polymers that contain pesticides as pendent side chains. The pesticide is presumably released by the slow sequential hydrolysis of the pesticide-polymer chemical bonds. . . . It was postulated that increasing the length of the pendent side chain would enhance the hydrolysis of the herbicide-polymer bond.").

Drobnik: p.2833 ("Water-soluble copolymers based on poly[N-(2-hydroxypropyl)methacrylamide] and bearing in their side chains a chromogenic substrate for chymotrypsin were prepared by direct copolymerization or polymeranalogous reaction."); p.2834 ("The bonding of drugs onto macromolecules is an old idea, because it offers a potential optimization of the pharmacokinetics of drugs. The majority of pharmaceuticals are inactive in the macromolecular form and must, therefore, be released in their original active low-molecular weight form, i.e. their attachment to the polymer must be reversible, or degradable."); p.2844-47 ("The results also indicate the general influence of the spacer: the longer the spacer, the easier the cleavage of the enzyme susceptibility bound For practical purposes, that is, enzyme-specific binding of drugs to polymers, the following conclusions can be drawn from the above results . . .").

Allan I: p.17 ("These materials are chemical or physical combinations of known and established pesticides with macromolecules. . . . As the pesticide-polymer combination lies in the soil, a gradual decomposition occurs, and the pesticide is slowly released over the desired and predictable period of time."); p.18-19 ("This situation is avoided by the use of a chemical combination of the butyric acid [herbicide] with the polymeric components of bark. The ester linkage joining the herbicide to the bark will not be easily attacked by any β -oxidase and the butyric acid herbicide is thereby stabilized. Essentially, the only butyric acid herbicide available for β -oxidation is that continuously being released from the bark. This release will occur whether the combination lies in or on the surface of the soil since attack by moisture, micro-organisms and the weather can occur in either of these zones.").

Allan II: p.349 ("We have therefore investigated the potential of pesticide-polymer combinations as a means of securing controlled release of a biodegradable pesticide in approximately the correct amount needed over an appropriate period of time. . . . Two distinct approaches are not reported. (a) Pesticide release by diffusion through polymers, and (b) pesticide release by degradation of a polymer containing the pesticide as a pendent side chain. . . . For case (b) the pesticides . . . are chemically attached as a pendent substituent to a natural or synthetic water-soluble or insoluble polymer . . ."); p.350 ("In the biological environment, side chain degradation occurs so that the chemical bonds holding the pesticide within its polymeric prison are sequentially broken to provide a sustained release of the pesticide over an extended period of time. The rate of release will clearly be determined by the nature of the pesticide-polymer bonds, the chemical characteristics of the pesticide and polymer and the dimensions and structure of the resultant macromolecular combination.") ("Although developed for developed for forest pest control the systems described should be broadly applicable to the controlled release of other biologically active substances.").

Allan III: p.173: ("Controlled release from polymeric matrix"); p.173-74 ("Representative of the other end of the thermodynamic spectrum is the situation where the pesticide is firmly attached to the substrate by a high energy covalent bond. Release of the pesticide then involves the cleavage of a definite identifiable chemical bond such as an ester or amide. . . . The simplest [arrangement] has the pesticide attached as a pendent substituent to a natural or synthetic water-soluble or insoluble polymer having a replaceable hydrogen The chemical bonds holding the pesticide within its polymeric prison are sequentially broken to provide a sustained liberation of the pesticide over an extended period of time."); p. 176 ("Moreover, the [controlled release] concept is broadly applicable to the release of other biologically active substances.").

Jakubke: p. 281 ("Observations in our laboratory indicated that an enzymatic cleavage of carrier-bound biologically active substance of low molecular weight is fundamentally possible. As part of a general model study of enzymatic reactions with insoluble substrates we investigated the α -chymotrypsin-catalyzed hydrolysis of Sepharose-bound L-phenylalanine 4-nitroanilide. As a spacer, 1 or 2 mol of 6-amino-hexanoic acid, respectively, were inserted between the gel matrix and the low-molecular weight substrate."); p. 282 ("The course of hydrolysis was proportional to time during the first 15 min. About 70% of total bound (ϵ Ahx)₂-Phe-NA was hydrolyzed after 4 hr."); Fig. 2 ("Dependence of hydrolysis on the enzyme concentration at 25°C."); p. 283 ("In agreement with this the substrate dependence of the hydrolysis rate shows the same course as observed with Glt-Phe-NA.").

Engelberg & Kohn: p. 292 ("For example, degradable polymers are now being investigated as intra-luminal grafts, stent-like devices that are implanted into coronary arteries in an attempt to prevent the collapse and the reblocking (restenosis) of blood vessels after successful balloon angioplasty."); p.293 ("Since surface-eroding, slab-like devices tend to release drugs embedded within the polymer at a constant rate, poly(ortho esters) appear to be particularly useful for controlled release drug delivery. It is not surprising that there are a significant number of publications describing the use of poly(ortho esters) for drug delivery applications."); p. 293-94 ("PLA, PGA and their copolymers are also being intensively investigated for a large number of drug-delivery applications. . . . PLA, PGA and their copolymers are currently the most widely used synthetic degradable polymers in human medicine."); p.294, Table 1; 294-95 (The potential applications of these [PHB polymers] include biomedical applications such as controlled drug release . . ."); p.295 ("Later, it was discovered that PCL can also be degraded by a hydrolytic mechanism under physiological conditions. Under certain circumstances, cross-linked PCL can be degraded enzymatically, leading to enzymatic surface erosion."); p.296 ("It is interesting to note that despite its versatility, PCL has so far been predominantly considered for controlled-release drug-delivery applications.") ("[The low hydrolytic stability] was later recognized as a potential advantage by Langer et al. who suggested the use of polyanhydrides as degradable biomaterials."); p. 297; p. 298 ("Poly(ortho esters)"); p. 298-99 ("PGA"); p. 299 ("PLA"); p. 300 ("PBH and copolymers with HV"); p. 301 ("PCL") ("Because of their low mechanical strength and high hydrolytic reactivity, the two polyanhydrides tested appear to be limited to drug-delivery applications."); p. 302.

Roseman & Mansdorf: p. 91-105 ("The objective of this chapter is to describe the development of a bioerodible polymer implant that would release an incorporated drug by zero-

order kinetics for at least 6 months. A further objective is the development of a system where drug release and polymer erosion take place concomitantly so that no polymer remains when the drug is depleted."); p. 107 ("There have been, however, studies where polymer-drug complexes have been synthesized, the major objective of which was to provide a controlled or prolonged action of the drug by the natural hydrolysis or biological scission of the covalent polymer-drug bond. In this way, mescaline, insulin, salicylic acid, D-isoproterenol, naloxone, plant cytokinins, 2,4-dichlorophenoxyacetic acid, norethindrone, and cortisol-21-acetate have been attached to and released from various synthetic and natural polymers through covalent bonds such as amide, ester, aso, carbamate, carbonate, oxime ester, and hydrazone."); p. 108 ("GAGs are biodegradable by enzymatic means normal to the host."); 108-109 ("We have taken advantage of various types of functional groups available on the GAG backbone (carboxyl, primary and secondary hydroxyl, and sulfate) in preparing and testing a series of complexes in which the drug was bound directly to the polymer or via an intermediate linking group such as an amino acid or other such bioacceptable entity. . . . Current work with other drugs bound to the GAG backbone by the same and different bond types (i.e., carbamate, ionic) will be reported in the near future."); p.110; p. 111 ("Amide and ester bond types were chosen because both are susceptible to chemical hydrolysis and both are prevalent naturally and thus are potentially dependable by enzymes."); p. 112 Fig. 2 & 3; p. 112-113 ("The release was pseudo-first order with a release rate constant of 0.10 day^{-1} and a half-life of 3.8 days. This is what one would expect if the rate-determining stem for release is the chemical hydrolysis of the ester bond in the prodrug."); p. 113 ("Reactions on polymers, such as the hydrolytic cleavage of GAG-drug bonds, has been shown to be affected by polymer chain length and conformation, steric isolation, and neighboring group effects."); p. 114; p. 115 ("Even though the amid bond between the drug and the polymer may hydrolyze slowly over this period and release cysteine, the rate-determining step for release was probably enzymatic breakdown of the complex. . . . A large advantage of using glycosaminoglycans as drug carriers is that they are biocompatible and biodegradable."); p.116 ("Chloramphenicol-GAG ester complexes released Cpl quickly by scission of the ester bond. Cysteine-GAG amide complexes degraded much more slowly and probably through enzymatic hydrolysis of the polymer or polymer-drug bond."); p. 117 ("Nevertheless, this concept provides an interesting base from which to design a drug release system; the rate of release may in principle be engineered by the judicious choice of drug-GAG bond based on the hydrolytic stability of the bond.").

Lee & Good: p. 2; p. 2-3 ("As a result of research on improved absorbable sutures, poly (lactic acid), poly (glycolic acid), and lactic/glycolic acid copolymers, which hydrolyze to natural metabolites, have been developed for drug delivery purposes."); p. 3 ("[P]olymer erosion can be controlled by the following three types of mechanisms: (1) water-soluble polymers insolubilized by hydrolytically unstable cross-links; (2) water-insoluble polymers solubilized by hydrolysis, ionization, or protonation of pendant groups; (2) hydrophobic polymers solubilized by backbone cleavage to small water soluble molecules. . . . [O]ther commonly used bioerodible/biodegradable polymers include polyorthoesters, polycaprolactone, polyaminoacids, polyanhydrides, and half esters of methyl vinyl ether-maleic anhydride copolymers.") ("Drug-Polymer conjugates. This system involve drug molecules chemically bounded to a polymer backbone. The drug will be released through hydrolytic or enzymatic cleavage. . . . The attachment of drugs to macromolecular carriers alters their rate of excretion from the body and provides the possibility for controlled release over a prolonged period. . . . Both natural

polymers such as polysaccharides and synthetic polymers such as polylysine, polyglutamic acid, polyphosphazenes, copolymers of vinylpyrrolidone, copolymers of 2-hydroxypropylmethacrylamide, and etc. have been used as drug carriers."); p. 4 ("The drug-polymer linkage may be covalent, ionic, or through some weaker secondary molecular forces. The drug may be part of the polymeric backbone or attached to the side-chain either directly or through a spacer group. The spacer groups is generally selected in such a way that it may be hydrolyzed or degraded enzymatically under specific environmental conditions. Examples of such drug-polymer conjugates include the attachment of ampicillin, 6-amino-methacrylamide copolymers, methotrexate to poly (L-lysine), and norethindrone to poly(hydroxyalkyl)-L-glutamine. In addition to diffusion rate limitations as described in the next section, the drug release rate is primarily governed by the rate of cleavage of the drug from the polymer."); p.5- 7 ("Matrix Diffusion"); p. 7 ("Polymer Erosion. The release of a dissolved or dispersed drug from an erodible polymer matrix can be controlled by a variety of mechanisms ranging from hydrolysis/enzymatic cleavage as discussed in the previous section to swelling and dissolution."); p. 17 ("An important example of these processes is the controlled release of bioactive molecules from polymeric membranes. Many pharmaceutically active agents have been released at controlled rates from hydrophobic polymer carriers. . . . In 1976 it was demonstrated that hydrophobic polymers, in particular ethylene-vinyl acetate copolymer (EVAc), could be used to release molecules with molecular weights greater than 1000."); p. 182 ("Enzyme-Degradable Hydrogel"); p.188-200; p. 214-230.

Langer & Folkman I: p. 179 ("Therefore, we turned to other polymers such as ethylene-vinyl acetate copolymer . . ."); p. 180-83; p. 183-84 ("Poly(vinylalcohol), Hydron, and ethylene-vinyl acetate copolymer were examined for their ability to release soybean trypsin inhibitor . . ."); p. 185-88; col. 188-191 ("The following three studies demonstrate that the pellets are releasing macromolecules in biologically active form."); p. 191-92 ("The present experiments show that macromolecules with a wide range of molecular weights can be delivered in significant quantities from polymeric vehicles that are not inflammatory when implanted in animals. These polymers can release macromolecules in biochemically and biologically active form for periods in excess of 100 days as measured by direct assays. . . . The eventual clinical application of these polymers for delivery of macromolecules such as insulin, heparin, or enzymes may merit consideration.").

Langer & Folkman II: p. 798-99 ("Polyvinylalcohol, Hydron and ethylene-vinyl acetate copolymer were examined for the ability to release soybean trypsin inhibitor . . .") ("These studies show that sustained release of proteins and other macromolecules from polymeric vehicles can be achieved over prolonged periods.").

Langer VIII: p. 1 ("One approach that has received increasing attention as a means of prolonging drug release has been the incorporation of drugs in solid polymers (e.g. silicone rubber, ethylene-vinyl acetate copolymer). This method permits drugs to be released for long time periods in a *controlled* fashion."); p. 10 ("Controlled-release polymer formulations may also find applications in other clinical areas. One such area that has received increasing attention is the controlled release of antibiotics. . . . Polymers have also been used to deliver anesthetics, anti-malarial drugs, anticoagulants, and drugs to combat cardiac arrhythmia."); p. 27 ("However, several recent studies have demonstrated that matrix systems can be engineered to permit

continuous release of large molecules. By solvent casting normally impermeable polymers such as ethylene-vinyl acetate copolymer in volatile solvents . . . along with powdered macromolecule, a series of interconnecting channels is formed within the polymer matrix. . . . These macromolecular delivery systems now open the possibility of delivering many important large molecular weight compounds such as insulin or interferon for prolonged periods."); Fig. 20; p. 28-29 ("[T]he volume of bioerodible systems becomes smaller with time, and, as the polymer surrounding the drug is eroded, the drug escapes."); p. 30 ("Erosion could be caused by hydrolytic or enzymatic cleavage of the crosslinks so that the ultimate degradation products are high molecular weight polymers. Alternatively, the degradation could occur in the polymer backbone so that the degradation products have low molecular weights."); p. 31-32 ("The third category of biodegradable systems are water-insoluble polymers that undergo hydrolytic or enzymatic backbone cleavage and are solubilized to small water-soluble molecules. . . . The best example of this class of polymer is polylactic acid or copolymers of lactic acid and glycolic acid."); p. 32 ("Sidman and coworkers . . . developed a peptide copolymer of glutamic acid and ethyl-*L*-glutamate."); p. 32-34 ("Pendant Chain Systems: In this type of system, a drug is chemically bound to a polymer backbone and is released by hydrolytic or enzymatic cleavage. The use of these therapeutic agents has received considerable attention in drug-related research. The major thrust so far has been the design of polymer-drug complexes for short-term use that can reduce toxicity, increase therapeutic efficiency, or be targeted towards specific cells or organs. . . . The drug itself can be attached directly to the polymer or it can be attached via a spacer group. The spacer group may be used to affect the rate of release and the hydrophilicity of the system. . . . To achieve near constant release, the cleavage of the drug from the polymer must be the rate-limiting step."); Fig. 22.

Langer & Folkman III: p. 114-15; p.117-18 ("Demonstration of Long-term Release") ("In initial trials with soybean trypsin inhibitor . . . protein was released . . . least rapidly from ethylene-vinylacetate copolymer."); p. 119-20 ("When tested in this fashion, ethylene-vinylacetate copolymer pellets continued to produce zones on these slides for over 100 days, indicating that the pellets were releasing nearly 1 ug/day or biochemically active protein."); p. 123-25 ("Insulin Delivery"); p. 125-26 ("Immunization Procedures").

Rhine: p. 265 ("Matrixes composed of ethylene-vinyl acetate copolymers are useful vehicles for the sustained release of macromolecules such as proteins These polymer systems had uniform drug distribution, and their release kinetics were reproducible."); p. 267 ("Therefore, macromolecules were added to a solution of polymer dissolved in a volatile solvent (methylene chloride). This mixture, when cast and dried, produced matrixes capable of sustained macromolecular release. . . . The reproducibility of release kinetics for matrixes prepared by low temperature methods was demonstrated for different proteins and for a range of particle sizes and loadings."); p. 268 ("A coating can also be used to control macromolecular release kinetics."); p. 269 ("Clinically, these systems may prove valuable as single-step methods for immunization or for the continuous delivery of insulin and other high molecular weight drugs.").

Aebischer: p. 282-83 ("Chemically inert polymer matrices, allowing controlled release of entrapped macromolecules over long time periods . . . open a new avenue of investigation. . . . The solvents used appear to have no detrimental effects on the biological activity of a number of

growth factors."); p. 283 ("Channel Fabrication"); p. 283 (disclosing the use of an impermeable outer coating which results in directional release of the treating factors into the lumen of the device); Table 1; p.286 ("The present study demonstrates that ethylene vinyl acetate copolymer can be fabricated into tubes with adequate physical properties for nerve entubulation and allows the controlled release of macromolecules.").

Langer IX: p.267 ("Two polymers suitable for sustained macromolecular release, poly(hydroxyethyl methacrylate), and alcohol-washed ethylene-vinyl acetate copolymer, were noninflammatory.") ("[W]e provide documentation that two polymers suitable for sustained macromolecular release, poly(hydroxyethyl methacrylate) (polyHEMA) and alcohol-washed ethylene-vinyl acetate copolymer, possess a high degree of biocompatibility in the rabbit cornea."); p.269; Table 1; p.276.

Langer X: p.179-80 ("Although we investigated several polymeric systems, the best results from the standpoint of tissue biocompatibility and long-term release (>100 days) were obtained with ethylene-vinyl acetate copolymer."); p.180 ("Biocompatibility studies"); p.181-87 ("In vitro and in vivo release kinetics"); p.192 ("Possible mechanisms of release of macromolecules") ("The absence of effect of ionic strength (fig7) suggests that osmotic pressure or charge interactions of drug with polymer have negligible roles in affecting release rates."); p. 195-200 ("Here, four studies exploring biomedical uses of these polymer systems are discussed. These include: (1) insulin delivery systems, (2) vehicles for immunization, (3) interferon delivery systems, and (4) systems for delivering anticancer or antiangiogenic macromolecules.").

Langer XI: p.95-96 ("Recent studies in our laboratory have demonstrated, however, that solvent casting of a variety of polymeric materials (ethylene-vinyl acetate copolymer, polyvinylalcohol, poly-2-hydroxymethyl-methacrylate) in the presence of powdered drug permits continuous release of macromolecules for over 100 days.").

Brown: p.1181 ("Macromolecules such as enzymes, antigens, and insulin have been released in biologically active form [from ethylene-vinyl acetate copolymers] for up to 6 months *in vivo*."); p. 1184 ("These data show that *in vivo* release can be accounted for by the same mechanisms operating *in vitro*; this should now make possible the further development and increased use of ethylene-vinyl acetate copolymer drug delivery systems.").

Kost & Langer: p.47-48 ("Bioerodible controlled systems."); p.48-49 ("Applications").

Hsu & Langer: p. 445-46 ("The current study shows the MW of EVAc copolymer is as important as drug loading and drug particle size in affecting the drug release kinetics. A release mechanism, which includes the properties of the polymer carrier, is proposed to serve as a guideline in selecting a suitable EVAc polymer carrier for a particular drug release device."); p.459.

Bawa: p.259 ("For example, EVAc polymers have been used as . . . delivery systems for insulin, interferon, and antigens."); p.263 ("Minimal effects exist due to osmosis or charge interaction of the drug with the polymer."); p.266 ("The data should be useful in the design of release vehicles for various polypeptides, polysaccharides, and other bioactive agents now produced by genetic engineering.").

Leong & Langer: p.202; p.203 ("The two common chemically controlled systems are a biodegradable matrix in which the drug is dispersed, and a polymer-drug conjugate in which the drug molecules are linked to the side chains of the polymer."); p.206-209 (describing use of biodegradable polymers for contraceptive systems); p.210-11 ("Against Ehrlich ascites carcinoma in rats, a sustained release of 5-fluorouracil from poly(ethylenevinylalcohol) is more efficacious than free drug administration."); p.211-14 ("Pendant systems"); p. 214-15 (use of EVAc for hormonal therapy and angiogenesis inhibition); 219-23 ("The clear demonstration of the feasibility [of sustained release of insulin from polymer] was later provided by a study using poly(ethylenevinylacetate) (EVAc).").

Baker: p.14-15 ("Diffusion-Controlled Monolithic Systems"); p.15-16 ("Biodegradable Systems"); p.161-65 ("Poly(ethylene vinyl acetate)").

Langer XII: p.162 ("In chemically controlled systems, release is accomplished either by biodegradation of the polymer or by chemical cleavage of the drug from a polymer backbone on which the drug had been bound as a pendent group."); p.163 ("A variety of reservoir and matrix devices are prepared from swollen crosslinked hydrophilic polymers (hydrogels). Most successful devices of this kind are based on poly (2-hydroxyethyl methacrylate) (HEMA) and related polymers although hydrophilic homopolymers of (poly vinyl 1-2-purrolidone) (PNVP), poly (vinyl alcohol) (PVA) and copolymers thereof have been tested with considerable success.") ("Ethylene-vinyl acetate (EVA) copolymers are prepared by emulsion copolymerization of ethylene and vinyl acetate. They are soluble in organic solvents and they can be used to prepare films or rods of dimensional stability and good mechanical strength."); p. 163-64 ("Biodegradable Polymers"); p.164-67 (clinical uses for controlled-release polymer systems).

Langer XIII: p.166; p.170 ("Studies have also been conducted to explore numerous applications of these systems. These include release of insulin . . . , anti-calcification agents . . . , interferons . . . , growth factors . . . and inhibitors . . . , and neurologically active agents.").

Chasin: p.43-44 ("In designing a biodegradable system that would erode in a controlled heterogeneous manner without requiring any additives, we have suggested that due to the high liability of the anhydride linkage, polyanhydrides may be promising candidates."); p.45 ("Molding procedures"); p.47-62 ("Kinetics of Drug Release") (describing release of various compounds); p.66-68 (polyanhydride safety and clinical studies).

Langer XIV: p.538-40 (describing polymers used in controlled release systems, including cellulose, poly(glycolic acid) and poly(lactic acid), poly(ortho esters), polyanhydrides, silicone rubber, ethylene-vinyl acetate copolymer, and poly(2-hydroxyethyl methacrylate)); 540-42 (describing clinical uses for controlled release systems).

Brem: p.2 ("The ethylene-vinyl acetate copolymer (EVAc) is an example of a non-biodegradable polymer while poly[bis(p-carboxyphenoxy) propane-sebacic acid] copolymer (PCPP-SA) and the fatty acid dimmer-sebacic acid copolymer (FAD-SA) are examples of biodegradable polymers."); p.3 ("Clinical applications for the EVAc polymer include drug delivery for contraception, insulin therapy, cancer chemotherapy, glaucoma treatment, dental caries prevention, and asthma therapy."); p.4-6 (describing in vivo and clinical studies of PCPP-SA and EVAc based delivery of chemotherapeutic drugs).

Langer XV: p.102 ("Our best long-term release results were obtained with relatively hydrophobic polymers, such as ethylene-vinyl acetate co-polymer or lactic glycolic acid copolymer, using methylene chloride as a casting solvent."); p.105 ("Therefore, we proposed to initiate studies on the development of a new class of bioerodible polymers: polyanhydrides."); p. 109 ("Through the NH₂ groups of lysine, specific amino acid sequences such as arginine-lysine-aspartic acid (RGD) have been chemically coupled to polylactic acid-co-lysine.").

Thompson: p.31-32; p.32 ("In this article, we include hydrolysis and enzymatic degradation under the heading of biodegradative processes."); p. 32-33 ("Collagen is one of the most widely used and best characterized of the natural biomaterials"); p.33 ("Gelatin, cross-linked with formaldehyde, has been studied in vitro as a drug delivery matrix . . ."); p.33-34 ("Starch"); p. 34 ("Furthermore, because of its hydrophilicity, cellulose has been utilized in pharmaceutical formulations to enhance water uptake and improve drug delivery.") ("The degradation of synthetic polymers is, in general, brought about by simply hydrolysis, although in some cases enzymatic processes assist in the degradation mechanism."); p.35 ("Since . . . the degradation characteristics of [poly(glycolic acid)] are predictable and reproducible, PGA has become a material of choice for many proposed applications calling for a synthetic biodegradable polymer.") ("Poly(L-lactic acid)"); p. 36 ("Poly (ε-caprolactone)") ("[Poly(orthoesters)] have therefore been exploited as constant rate drug delivery devices.") ("Poly(anhydrides)"); p.36-41 ("Hydrophobic polymers") ("Poly(ethylene)"); p. 41-44 ("Hydrophilic Polymers") ("Poly(2-hydroxyethyl methacrylate)"); p.44 ("Natural and synthetic biodegradable polymers have been utilized in drug delivery and tissue engineering. Drug delivery systems based on biodegradable polymers facilitate the controlled release of drugs with the concurrent degradation of the polymer.").

Chandrasekaran: p.587 ("The simplest to a bioerodible drug delivery system is to disperse or dissolve the drug in a water-soluble polymer, which will slowly erode in an aqueous medium Another approach involves the synthesis of hydrophobic water-insoluble polymers in which the major fraction of the drug is released by erosion of the polymer matrix . . ."); p.588 ("Hydrophobic polymer solubilization can be achieved as a result of a chemical reaction that takes place at either a pendant group of the polymer or within the polymer backbone. When the reaction is confined to the pendant group, no backbone cleavage takes place, and one of the reaction products is a hydrolytically stable water-soluble polymer. . . . Hydrophobic polymers can also be solubilized by an ionization reaction of pendant carboxyl groups; drug dissolution and release rate kinetics are obtained from partially esterified copolymers derived from ethylene-maleic anhydride or methyl vinyl ester-maleic anhydride.").

Kim: p194-96; Fig.4; 197-201 ("Drug Diffusion through Polymers"); p.202-204 ("Release Rate from Monolithic Devices"); p.204-206 ("Mechanistic Considerations of Drug Diffusion through Polymer Membranes"); p.215-220 ("Hydrophobic Polymers as Drug Carriers") ("Ethylene-Vinyl Acetate Copolymer (EVA)"); p.220-23 ("The synthesis of biodegradable polymers for controlled drug release is based on different strategies. 1. A degradable polymer medium to which a drug is dispersed. Here drug diffusion through the polymer matrix is influenced by the degradation of the polymeric material. 2. A degradable polymer medium to which a drug is attached through a hydrolytically labile linkage. Drug release is controlled by both hydrolysis of the drug from the polymer and by diffusion of the

drug through the polymer matrix."); p.226-28 ("Design of Chemically Bound Polymer-Bioactive Agent (PBA) Systems"); p.228-29 ("Models of Chemically Bound Polymer-Bioactive Agent Systems."); p.229-46 ("Examples of Chemically Bound Polymer-Bioactive Agent Systems").

Dev: Abstract; p. 273 ("The purpose of this study was twofold: first, to test a polymer-coated removable stent system for local delivery of two lipid soluble drugs . . . and second, to compare these two drugs with respect to kinetics of their delivery to the arterial wall with the stent in place and their tissue washout rates after removal of the stent."), ("We used a commercially available biomedical grade polyurethane [as a stent coating]. . . . To study the kinetics of drug delivery, we used two lipid soluble compounds: forskolin and etretinate."), ("Ratio of peak drug levels in the vessel wall to those in the blood was 6,000 for etretinate and 780 for forskolin. . . . Polymer-coated stents could be used for local drug delivery to the vessel wall."); p. 274-75 ("the drug levels [of etretinate] in blood and the distant tissues are extremely low, and the ratio of local to systemic drug levels is very high (~6,000); p. 277 ("This [preferential release of drug into the arterial wall] may reflect slower diffusion of etretinate in the aqueous medium than forskolin or presence of significant tissue binding of etretinate.").

Claim 15 [15E] (cont'd): the device being flexible in three dimensions by manipulation by human hands,

Where Found in the Prior References:

Peterson '166: Col. 2:51-54 ("Typical polymeric carriers are polyesters, polyamides, polyurethanes and other condensations polymers . . .").

Schwartz '823: Abstract ("A radially expandable stent . . . the cylindrical body comprising a plurality of metal elements joined to allow flexing of the cylindrical body along the longitudinal axis of the body whereby the stent can conform to a curved body lumen . . ."); col. 1:9-14; col. 1:17-19; col. 1:53-55; col. 2:16-19 ("It is therefore an object of the present invention to provide a stent having longitudinal flexibility which allows it to conform to curves and variation in body lumens."); col. 2:29-40; col. 2:44-49; col. 3:48-57; col. 3:58-64 ("The improvement of the present invention includes applying to the above-mentioned type of stent a flexible or elastomeric polymeric film which extends between the metal elements."); col. 4:20-27 ("The term 'film' or 'flexible film' herein therefore means that, as applied to the metal stent elements in a thin cross section, the film is capable of flexing or stretching to preserve the radial expandability and axial flexibility of the implanted stent."); col. 4:49-5:41 ("It also produces a stent having a flexible film which extends between the metal elements of the stent and which will not significantly affect the ability of the stent to conform to curved body lumens. . . . A suitable crimping tool . . . may be used to tighten the stent over the balloon. A manual operation of sequentially squeezing the stent over the balloon is also acceptable."); col. 5:65-6:1; col. 6:17-20; col. 6:30-32; col. 6:43-47; col. 6:49-52; col. 6:58-68; col. 8:19-41.

Scott '928: Col. 8:23-60 (disclosing use of EVA).

Tartaglia '113: Abstract; col. 1:15-19 ("Ideally, implantation of such stent is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:57-60 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member."); col. 1:64-67 ("The polymer material can be a thermoplastic or an elastomer, for example, so that the film can stretch or deform radially when the stent structural member is expanded."); col. 2:23-33; col. 2:48-55; col. 5:6-10; col. 6:54-56; col. 7:18-21 ("The apertures also improve the flexibility of the polymeric material, allowing the stent segment to be more easily rolled and uncoiled during expansion of the stent structural member . . ."); col. 10:40-47.

Wolff '208: Col. 2:7-9 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 9:39-42 ("The device is fixed into place either by radial expansion in devices such as shown in Fig. 1 or are deformed by a balloon catheter in the case of devices in accordance with Fig. 2."); col. 10:3-45 ("The stents are arranged on the distal end of the catheter such that the catheter can provide remote, transluminal deployment of the stents, with the metal stent inside the polymeric stent, from an entry point into a selected portion of the body lumen to be treated and also remote actuation of an expansion mechanism from the proximal end of the catheter. The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen."); col. 10:51-57; col. 10:66-11:3 ("The metal stent is crimped onto the balloon and includes an elongated lead extending to the proximal end of the catheter assembly where it includes an enlarged portion to enable an operator to securely grip the lead."); col. 12:1-15.

Berg '354: Page 2:14-15 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen."); p.3:18-22 ("The transluminal delivery can be accomplished by a catheter designed for the delivery of stents and the radial expansion can be accomplished by balloon expansion of the stent, by self-expansion of the stent, or a combination of self-expansion and balloon expansion. Thus the present invention provides a stent which may be delivered and expanded in a selected blood vessel without losing a therapeutically significant amount of a drug applied thereto."); p. 5:28-29.

Buscemi '450: Col. 1:58-60; col. 7:10-20 (" . . . said tubular main body including a slot extending lengthwise through the main body and defined by opposing edges of the main body wherein the opposing edges must be moved toward each other under compression in order to transport the biodegradable stent through a vessel of a living being . . ."); col. 8:18-24.

Ding '536: Col. 1:48-51 ("One type of self-expanding stent has a flexible tubular body formed of several individual flexible thread elements each of which extends in a helix configuration with the centerline of the body serving as a common axis."); col. 3:5-9; col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 3:56-64 ("... the tubular body is formed of a self-expanding open braid of fine, single or polyfilament metal wire which flexes without collapsing, readily axially deforms to an elongate shape for transluminal insertion via a vascular catheter and resiliently expands toward predetermined stable dimensions upon removal in situ.").

Dinh '227: Col. 1:32-35 ("The stent is typically inserted by catheter into a vascular lumen told [sic] expanded into contact with the diseased portion of the arterial wall, thereby providing mechanical support for the lumen."); col. 2:62-66 ("The inclusion of a polymer in intimate contact with a drug on the underlying stent structure allows the drug to be retained on the stent in a resilient matrix during expansion of the stent and also slows the administration of drug following implantation."); col. 3:14-22; col. 6:62-67; col. 7:13-21; col. 8:29-43 ("For example, a deformable metal wire stent such as that disclosed in U.S. Pat. No. 4,886,062 issued to Wiktor could be coated with fibrin as set forth above The stent and fibrin would could then be placed onto the balloon at a distal end of a balloon catheter and delivered by conventional percutaneous means . . . to the site of the restriction or closure to be treated where it would then be expanded into contact with the body lumen by inflating the balloon."); col. 8:49-52 ("A catheter has a balloon upon which a stent has been placed, the stent having a deformable metal portion and a fibrin coating, thereon."); col. 8:64-9:2; col. 9:18-24; col. 9:49-50 ("The resulting fibrin stent includes the stent embedded in a very thin elastic film of fibrin."); col. 9:59-63; col. 12:24-28.

Domb '055: Abstract ("Preferred embodiments include catheters, tubes, and implants that abut tissue following implantation into the body . . ."); col. 4:25-32; col. 5:27-37 ("In a particularly preferred embodiment, polymers incorporating steroids are coated onto devices including tracheal T-tubes, stoma stents, laryngeal/bronchial stents, laryngeal keels, and nasogastric tubes."); col. 5:46-54; col. 5:60-62; col. 7:10-20; col. 7:40-52; col. 9:15-30; col. 9:55-10:2; col. 10:21-52; col. 10:60-11:11.

Fox '096: Col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages.").

Hunter '981: Col. 16:31-56; col. 17:63-18:7 ("[T]he anti-angiogenic compositions of the present invention may be formed as a film. . . . Such films are preferably flexible with a good tensile strength . . . and has controlled permeability."); col. 22:3-7; col. 22:21-39; col. 22:54-58; col. 23:26-30; col. 60:35-45; Fig. 17E; col. 66:13-22 ("As discussed above, sterile, pliable, stretchable drug-polymer compounds (e.g., films) may be utilized in accordance with the

methods described herein in order to isolate normal surrounding tissues from malignant tissue during resection of cancer.").

Kowligi '782: Col. 4:28-37.

Lambert '922: Col. 3:54-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected.)"); col. 8:1-6.

Lambert '308: Page 6:21-28 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected.)").

Myler '563: Abstract ("When elongated in an axial direction, the stent is reduced in cross-sectional area."); col. 2:13-16 ("The stent is configured to permit radial expansion, such as under the force generated by balloon dilation, and radial contraction in response to axial elongation."); col. 2:22-26; col. 2:27-28; col. 3:13-15; col. 3:33-34; col. 3:44-46; col. 3:48-51 ("Alternatively, tubular stents formed from flexible non-metal materials such as elastomeric polymers or rubber (latex) can also be radially reduced by axial elongation in accordance with the present invention."); col. 3:58-61; col. 4:9-12; col. 4:30-43 ("Suitable envelope materials include elastic materials such as latex and others that can be readily selected by one of skill in the art. . . . In general, biocompatible materials which can tolerate expansion of the stent between the insertion diameter and expanded diameter can be used."); col. 5:1-16; col. 5:50-54; col. 6:18-23; col. 10:12-14 ("The balloon is inflated, thereby expanding the stent radially outwardly until it contacts either a previously dilated, or presently stenosed wall."); col. 11:55-58; col. 11:63-65; col. 12:11-13; col. 12:19-23; col. 12:63-13:1 ("Suitable coating materials include elastic materials such as polyethylene or PET or other materials that can be readily selected by one of skill in the art. In general, any biocompatible material which can tolerate expansion of the stent between the insertion diameter and treatment diameter can be used."); col. 13:61-66; col. 19:18-30; col. 19:65-20:7; col. 20:51-57.

Palmaz '417: Abstract ("A plurality of expandable and deformable intraliminal vascular grafts are expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 1:17-23 ("The invention relates to an expandable intraliminal graft for use within a body passageway or duct and, more particularly, expandable intraliminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease; and a method and apparatus for implanting expandable intraliminal grafts."); col. 3:56-4:7; col. 4:28-37; col. 5:4-5:20 ("The present invention includes: a plurality of expandable and deformable, thin-walled tubular prostheses . . ."); col. 5:41-43; Fig. 10; Fig. 9; col. 6:6-9; col. 6:20-22; col. 6:63-7:2; col. 7:64-8:2; col. 8:36-60; col. 10:6-14; col. 10:55-58 ("Disposed between adjacent tubular members, or adjacent grafts, or prostheses, is at least one connector member to flexibly connect adjacent tubular members, or grafts, or

prosthesis."); col. 12:19-21; col. 12:33-38; col. 12:41-63 ("As seen in Fig. 9, because of the disposition of flexible connector members between adjacent tubular members 71, or grafts, or prostheses 70, graft, or prosthesis 70' is able to flexible bend or articulate, with respect to the longitudinal axis of graft, or prosthesis, 70', so as to be able to negotiate the curves or bends found in body passageways. . . . It should be noted that connector members permit the bending, or articulation, of adjacent tubular members in any direction about the longitudinal axis of graft, or prosthesis."); col. 12:64-66; Fig. 10; col. 12:66-13:2; col. 13:22-24; col. 13:31-40; col. 14:17-19; col. 14:27-29; col. 14:41-43; col. 14:48-59; col. 15:18-30; col. 15:33-40; col. 15:61-63; col. 15:67-16:6; col. 16:20-29; col. 16:34-37; col. 16:45-54; col. 16: 59-67.

Aebischer '486: Col. 3:56-63.

Schiraldi '243: Col. 1:8-21 ("The extruded film drug delivery system of the present invention, which has incorporated therein the medicament to be dispensed, is so thin and flexible when wet as to be unobtrusive to the patient after it has been properly positioned and placed in the mouth."); col. 2:30-51.

Valentini '029: Col. 1:56-2:4; col. 2:29-41 ("The devices can be formed from various polymeric materials, such as acrylic copolymers, polyvinylidene fluoride or polyurethane isocyanate, adapted to receive the ends of the severed or otherwise damaged nerve."); col. 3:62-67 ("The sheet is then wrapped around the nerve segments and the resulting tube is closed by further sutures, adhesives or friction."); col. 4:46-59 (disclosing use of flexible polymeric materials).

Wood '066: Abstract; col. 2:56-3:17; col. 7:51-65; col. 17:19-22; col. 17:30-34 (" . . . to give a flexible, elastomeric, white cryogel membrane . . ."); col. 18:1-4; col. 18:13-16; col. 18:26-30.

Strecker '746: Abstract ("An endoprosthesis in the form of an elongated hollow structure . . . once correctly positioned will expand from an initial state with a narrow lumen into a state with a lumen that is as wide as its placement will allow. It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen."); col. 1:12-22 ("Once correctly positioned it will expand from an initial state with a narrow lumen into a state with a lumen that is as wide as its placement will allow. . . . The lumens can be expanded by mechanically stretching them with a known balloon catheter. They can also be compressed prior to implantation and stretch out on their own subject to the resilience introduced by the compression."); col. 1:63-2:2; col. 2:21-32; col. 2:33-38; col. 2:65-3:4; col. 6:30-32; col. 7:16-35; col. 8:19-10:19.

Lambert '246: Col. 3:55-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected.)").

Bellamkonda '029: Col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making

same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 4:48-57; col. 10:32-40; col. 11:33-40.

Dayton '382: Abstract ("The device comprises a stent which is formed from metal or polymers into a predetermined shape which includes a plurality of holes . . . to provide a desired bending modulus."); col. 3:62-4:12; col. 4:42-50; col. 4:54-5:3; col. 8:42-59.

Burt '036: p.14:9-27; p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size.").

Goldin '568: Col. 1:55-62 ("Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:8-12; col. 2:24-29 ("Microporous membranes for release of proteins by controlled diffusion have been fabricated from ethylene vinyl acetate (EVA) . . .").

Palmaz '665: Abstract ("An expandable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 1:11-17; col. 3:3-7; col. 3:33-39; col. 4:1-6; col. 4:33-36; col. 6:4-11; col. 7:20-25.

Palmaz '762: Abstract ("An expandable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 3: 45-51 ("...upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular shaped member may be expanded and deformed to expand the lumen of the body passageway."); col. 4: 14-19; col. 4: 43-46; col. 5: 43-45; col. 6: 18-24; col. 8: 7-21.

Palmaz '337: Abstract ("An expandable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel."); col. 3: 37-44 ("... and the tubular shaped member having a second, expanded diameter, upon the application from the interior of the tubular shaped member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular shaped member, whereby the tubular shaped member may be expanded to expand the lumen of the body passageway."); col. 3:60-4:2 ("The method of the present invention comprises the steps of: ... and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded, ..."); col. 8: 17-22.

Zaffaroni '254: Col. 7: 5-8 ("Device 10 is capable of being substantially straightened by passing through a hollow instrument for positioning it in the uterus 25.").

Aebischer: p. 284 (disclosing manipulation of polymer tube to allow entry of nerve stumps).

Dev: p. 273 ("We used a commercially available biomedical grade polyurethane . . . Tecoflex is a biocompatible, flexible, and an elastic membrane-forming polymer.").

Claim 15 [15F] (cont'd): the device being capable of substantially restricting the through passage of at least one type of macromolecule therethrough;

Where Found in the Prior References:

Schwartz '823: Abstract; col. 2:29-40; col. 2:49-53; col. 3:58-61 ("The improvement of the present invention includes applying to the above-mentioned type of stent a flexible or elastomeric polymeric film which extends between the metal elements."); col. 3:64-4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof."); col. 6:17-20; col. 7:25-8:11.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); Fig. 3; col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-33; col. 5:34-6:29; col. 6:37-41; col. 6:41-45 ("Modifications of the polymer coating include a ring that encompasses the proximal portion of the stent, single or multiple strips that cover a portion of the stent, or a polymer coating with perforations."); col. 8:23-25 ("Ethylene vinyl acetate copolymer (EVA) (Catalog #34,691-8) was obtained from Aldrich Chemical Company, Inc. (Milwaukee, Wis.); col. 10:24-33; col. 12:1-6; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow Controlled release of the drug.").

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Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Col. 1:7-10 ("This invention relates generally to expandable intraliminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 1:64-2:2 ("The polymer material can be a thermoplastic or an elastomer, for example, so that the film can stretch or deform radially when the stent structural member is expanded. The film of polymer material can be formed as a solid sheet, or can incorporate holes of various sizes and shapes to promote rapid endothelialization."); col. 4:15-24; col. 4:25-46; col. 4:47-5:3; col. 5:4-9; col. 5:49- 6:25 ("The polymeric material is preferably selected from thermoplastic and elastomeric polymers. . . . In another currently preferred embodiment, the polymeric material can be ethylene vinyl acetate (EVA) . . ."); col. 6:26-65; col. 7:23-42; col. 7:63-65; col. 8:12-57; col. 9:5-12; col. 10:12-30.

Wolff '208: Col. 2:7-16 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:28-30 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 6:59-62 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously. The polymer may be biostable or bioabsorbable. If biostable, the drug would diffuse out of the polymer."); col. 6:64-67; col. 7:59-61; col. 9:23-33 ("That layer may be a simple barrier which limits diffusion of drugs in the polymer. In that event, the smaller molecules could elute out immediately, while larger compounds would not elute until later when the layer has biodegraded."); col. 12:37-40 ("8. The device of claim 1 also comprising a barrier coating of polymeric material on the drug-containing filament to limit the rate of drug elution.").

Berg '354: Page 2:43-54 ("Viewed from a further aspect the invention provides the use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug-eluting surface coating."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:29-31 ("Also, stents made with biostable or bioabsorbable polymers such as poly(ethylene terephthalate), polyacetal, poly(lactic acid), poly(ethylene

oxide)/poly(butylene terephthalate) copolymer could be used in the present invention. "); Table 1; p. 4:5-24; p. 6:6-11; p. 6:15; p. 6:24-35; p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Abstract ("A stent made of biodegradable material includes a drug that is released at a rate controlled by the rate of degradation of the biodegradable material."); col. 2:16-17; col. 4:1-5 ("In one embodiment, the main body includes a film that is preferable combined with the plurality of fibers disposed around the main body. The film combined with the plurality of fibers defines the outer surface of the main body."); col. 4:15-16 ("Preferable, the main body of the stent includes a film covering the inner surface."); col. 4:19-22.

Ding '536: Abstract ("The coating includes a relatively thin layer of biostable elastomeric material containing an amount of biologically active material, particularly heparin, dispersed in the coating in combination with a non-thrombogenic surface."); col. 1:24-29 ("The present invention relates generally to providing biostable elastomeric coatings on the surfaces of implants which incorporate biologically active species having controlled release characteristics in the coating particularly to providing a non-thrombogenic surface during and after timed release of the biologically active species."); col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 5:10-56 ("Polymers generally suitable for the undercoats or underlayers include silicones (e.g., polysiloxanes and substituted polysiloxanes), polyurethanes, thermoplastic elastomers in general, ethylene vinyl acetate copolymers, polyolefin elastomers, polyamide elastomers, and EPDM rubbers. The above-referenced materials are considered hydrophobic with respect to the contemplated environment of the invention."); col. 12:62-13:2; col. 13:13-26; col. 13:37-40; col. 14:5-17; col. 14:22-34.

Dinh '227: Col. 2:51-54 ("To accomplish this while not affecting the strength of the overall fibrin stent structure, a first layer is applied to a stent body, the first layer incorporating a polymer and the therapeutic substance."); col. 2:62-66 ("The inclusion of a polymer in intimate contact with a drug on the underlying stent structure allows the drug to be retained on the stent in a resilient matrix during expansion of the stent and also slows the administration of drug following implantation."); col. 3:10-14; col. 3:25-38; col. 5:3-7; col. 5:44-55; col. 5:56-57; col. 6:13-19 ("In U.S. Pat. No. 4,548,736 issued to Muller et al., a dense fibrin composition is disclosed which can be a bioabsorbable matrix for delivery of drugs to a patent. Such a fibrin composition can also be used in the present invention by incorporating a drug or other therapeutic substance useful in diagnosis or treatment of body lumens to the fibrin provided on the stent."); 6:50-56 ("Alternatively . . . a dense fibrin composition suitable for drug delivery can be made without the use of microcapsules by adding the drug directly to the fibrin followed by compression of the fibrin into a sufficiently dense matrix that a desired elution rate for the drug is achieved."); col. 6:62-67; col. 7:10-13; col. 7:56-64 ("In another embodiment of the invention, the coating of polymer and drug on the stent is achieved by forming a first fibrin layer on the stent body which incorporates the therapeutic substance and then applying a second layer of

fibrin."); col. 8:52-60 ("Fig. 2 shows an alternative stent in which a fibrin film has been affixed to the underlying metallic framework by affixing it to the stent . . ."); col. 8:64-9:3; col. 12:24-28; col. 12:38-50.

Domb '055: Abstract ("Devices are provided having a polymer coating incorporating compounds inhibiting inflammation and infection, along with subsequent tissue growth onto and around the device. . . . Preferred polymeric coating are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); col. 1:12-15 ("This invention relates to invasive medical devices for delayed/sustained release of pharmaceutical compositions from a polymer that is coated or incorporated into the devices."); col. 3:54-57 ("In the preferred embodiments, these have utilized bioerodible polymers as the matrix for the drug to be released, usually as a function of diffusion and erosion of the polymer."); col. 4:22-36; col. 5:24-37; col. 5:41-45; col. 5:48-6:1; col. 6:24-26 ("Examples of suitable polymers include ethylene vinyl acetate, polyurethane, silicones, hydrogels, polyurethane, and polyvinyl chloride."); col. 7:10-20; col. 7:40-52; col. 9:15-30; col. 9:55-10:2; col. 10:21-52; col. 10:60-11:11; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 11:36-38 ("The medical device of claim 1, wherein the polymer is selected from the group consisting of polyurethane, ethylene vinyl acetate, silicones, hydrogels, and polyvinyl chloride."); col. 11:39-44; col. 12:11-22; col. 12:23-25; col. 12:26-31; col. 12:32-42.

Fox '096: Abstract ("A method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers, and antimicrobial agents . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 2:48-65; col. 3:55-67 ("The polymeric coating agent component of the coating vehicle of the present invention is selected from the group consisting of biomedical polyurethanes, biomedical silicones, biodegradable polymers and combinations thereof."); col. 19:11-16; col. 31:62-64.

Hunter '981: Col. 1:12-17; col. 3:42-45 ("Within one aspect of the present invention, compositions are provided (anti-angiogenic compositions) comprising (a) an anti-angiogenic factor and (b) a polymeric carrier."); col. 3:53-61; col. 12:23-25 ("As noted above, the present invention provides compositions comprising an anti-angiogenic factor, and a polymeric carrier."); col. 16:31-56; col. 17:63-18:7 ("[T]he anti-angiogenic compositions of the present invention may be formed as a film. . . . Such films are preferably flexible with a good tensile

strength . . . and has controlled permeability."); col. 22:3-7; col. 22:54-58; col. 47:58-49:7; col. 52:4-8; col. 69:19-62; col. 84:62-86:24; 86:56-59; col. 87:11-22; col. 88:19-26.

Kowligi '782: Abstract ("The elastomeric coating is made of polyurethane or another biocompatible non-porous elastomers and precludes tissue ingrowth into the outer cylindrical wall, minimizes suture hold bleeding, and increases suture retention strength, while reducing the incidence of serous weepage."); col. 1:18-26; col. 2:15-20; col. 2:38-47; col. 2:53-59; col. 3:27-37; Fig. 1; Fig. 2; Fig. 3; col. 2:60-67 ("PTFE tube 32 includes an inner cylindrical wall and an opposing outer cylindrical wall. As shown in Fig. 2, outer cylindrical wall 36 is coated entirely around its circumference by a uniformly thick coating of a biocompatible elastomer."); col. 3:27-38; col. 4:16-27 ("In regard to elastomeric coating 38 shown in Fig. 2, such elastomeric coating is selected to be a biocompatible elastomers and may be selected from the group consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 4:37-39 ("The elastomeric coating should also be sufficiently non-porous to preclude serous weepage and inhibit tissue ingrowth therethrough."); col. 5:4-7; col. 7:49-8:9; col. 8:38-44; col. 9:65-10:6; col. 10:18-24; col. 10:33-42; col. 10:43-50; col. 10:51-59; col. 10:60-67.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 2:16-35; col. 2:40-50; col. 3:8-12; col. 3:29-32; col. 3:33-49; col. 3:55-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); col. 7:29-32; col. 7:38-41; col. 10:57-64; col. 11:49-51; col. 11:65-12:13; col. 12:43-64; col. 13:13-19.

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p. 3:10-31 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); p. 4:2-12; p. 6:21-28 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); claim 1:1-14; claim 8:1-5; claim 10:1-3; claim 11:1-13; claim 22; claim 23:1-14; claim 19:4-31.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8.

Myler '563: Col. 2:10-13; col. 3:13-15; col. 3:52-54; col. 4:30-43 ("In a preferred embodiment, the interior and exterior walls of stent 10 are enclosed in a thin polymeric envelope. . . . Suitable envelope materials include elastic materials such as latex and others that can be readily selected by one of skill in the art."); col. 5:1-16; col. 5:39-41 ("For the above reasons, even the expanded pores for drug delivery should be small enough to maximize or prevent cell penetration, but large enough for drug delivery."); col. 12:11-13; col. 12:19-23; col. 12:28-33 ("Suitable materials include elastomeric polymers or natural rubber (latex). . . . Polymeric stents can be provided with relatively fluid impenetrable walls, or porous walls such as to allow drug delivery, as will be apparent to one of skill in the art."); col. 12:63-65 ("Suitable coating materials include elastic materials such as polyethylene or PET or other materials that can be readily selected by one of skill in the art."); col. 18:51-19:9; col. 19:18-30; col. 19:31-32; col. 19:61-63; col. 20:33-49; col. 20:51-57.

Palmaz '417: Col. 6:66-68; col. 11:3-14 ("Examples of a suitable biologically compatible coating would be porous polyurethane, Teflon™ or other conventional biologically inert plastic materials."); col. 11:26-31 ("Examples of biologically compatible coatings would include coatings made of absorbable polymers such as those used to manufacture absorbable sutures. Such absorbable polymers include polyglycoides, polyacoides, and copolymers thereof.").

Tice '330: Col. 3:20-33 ("Suitable wall forming materials include polystyrene, ethylcellulose, cellulose acetate, hydroxyl propylmethylcellulose phthalate, cellulose acetate, dibutylaminohydroxypropyl ether, polyvinylbutyral, polyvinyl formal, poly(meth)acrylic acid ester, polyvinylacetal-diethylamino acetate, 2-methyl-5-vinyl pyridine methacrylate-methacrylic acid copolymer, polycarbonate, polyesters, polypropylene, vinylchloride-vinylacetate copolymer, polysaccharides, glycerol distearate, and the like. A preferred group of polymeric wall forming materials includes those which are biodegradable such as aliphatic polyesters including polylactide, polyglycolide, polycaprolactone and copolymers thereof."); col. 8:38-51.

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); col. 3:7-18; col. 3:56-63; col. 4:31-34 ("The outer membrane surface is nonporous, while porous inner membrane surface allows for the diffusion therethrough of active factor 26."); col. 5:18-28 ("In a preferred embodiment of the invention, the outer surface of the membrane is impermeable to solutes of any size, while the inner membrane surface contains pores [that] enable the active factors to diffuse out of the membrane and into the lumen of the channel."); col. 6:17-22 ("The layering procedure allows deposition of an impermeable coat on the outer surface of the device, insuring that the active factors incorporated into the membrane walls will be inhibited from diffusing through the external surface, and will diffuse only through the inner membrane surface into the lumen of the channel."); 6:54-61; col. 9:18-10:3.

Folkman '560: col. 2:43-68 ("A biocompatible plastically deformable polymer matrix . . . substantially impermeable to a macromolecule"); col. 3:18-23 ("The polymer matrixes, which are suitably used in the present invention, are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:36-51 ("Typical polymeric material suitable for forming the matrix . . . include . . . alkylene-vinyl acetate copolymers . . . crosslinked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:52-4:26 ("In the presently preferred embodiment the polymeric materials useful for forming the matrix are the ethylene vinyl ester copolymers of the general formula . . ."); col. 11:56-12:20.

Cohen '496: Col. 3:26-45 ("The polymer matrices . . . are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:65-4:39 ("In a presently preferred embodiment, the polymeric materials useful for forming the matrix are the ethylenevinyl ester copolymers of the general formula . . ."); col. 9:40-10:17; col. 10:18-32.

Schiraldi '243: Col. 1:8-21 ("The extruded film drug delivery system of the present invention, which has incorporated therein the medicament to be dispensed, is so thin and flexible when wet as to be unobtrusive to the patient after it has been properly positioned and placed in the mouth."); col. 1:58-60; col. 2:30-51; col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 9:36-55; col. 10:12-18.

Valentini '029: Abstract ("Medical devices employing semipermeable materials, such as acrylic copolymers, polyurethane isocyanate, and other biocompatible semipermeable polymers, are disclosed for use as guidance channels in regenerating nerves. . . . The guidance materials are chosen such that they are capable of allowing the diffusion of nutrients and other metabolites to the regenerating nerve site while excluding fibroblasts and other scar-forming cells."); col. 2:29-57 ("It has been discovered that the repair of severed or avulsed nerves can be greatly enhanced by the use of selectively permeable polymeric materials as nerve guidance channels. . . . The devices can be formed from various polymeric materials, such as acrylic copolymers, polyvinylidene fluoride or polyurethane isocyanate Preferable, the materials allow passage therethrough of solutes having a molecular weight of about 100,000 daltons or less. . . . The nerve guidance channels of the present invention are also preferably designed to retain nerve growth factors secreted at the anastomatic site or seeded therein, as well as retain any luminal matrix material placed inside the guidance channels."); col. 2:58-3:14; col. 4:46-59; col. 5:13-32 ("The success rate and quality of peripheral nerve regeneration was dramatically enhanced

through the use of a semipermeable material."); col. 5:42-6:12 ("The permselective characteristics of the inner membrane allow the exchange of nutrients, while concentrating growth factors released by the nerve and excluding scar-forming cells."); col. 6:14-24; col. 6:31-42.

Greco '135: Col. 3:48-4:1 ("These devices will consist of organic polymers and/or metallic materials including: . . . polyethylene . . . elastomeric organosilicon polymers, such as polysiloxanes, e.g. Silastic ®").

Aebischer '627: Col. 3:57-4:3 ("The polymeric insert includes pores having a molecular weight exclusion of from about 1 kD to about 1,000 kD, but preferably from about 25kD to about 100 kD."); col. 4:11-27 ("The terms 'semipermeable' is used herein to describe biocompatible membranes that allow the diffusion therethrough of molecules having a relatively low molecular weight, while excluding the passage of those having a relatively high molecular weight. . . . The semipermeable membrane can be made of various polymeric compositions such as polyvinylchloride, polyacrylonitrile, polyvinylidene fluoride, polystyrene, polymethylmethacrylate, polysulfone, and acrylic copolymers."); col. 7:57-8:14 ("In this embodiment, a semi-permeable membrane functions as a protective cell culture device for the neurotransmitter-secreting cells. The pores of the membrane should be large enough to enable the exchange of metabolites with body fluids, and to permit the diffusion therethrough of neurotransmitter produced by the cells therein, but are small enough to bar the passage therethrough of larger elements deleterious to the cells."); col. 13:31-48; col. 13:66-68; col. 14:1-2; col. 14:22-28; col. 14:54-56.

Wood '066: Abstract ("A controlled-release bandage containing therapeutic agents in a poly(vinyl alcohol) cryogel is disclosed. The bandage may include . . . hydrophobic particles to further insure controlled and constant release of therapeutic agents."); col. 2:56-66; col. 23:4-11.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:63-2:2; col. 2:12-15 ("The present invention on the other hand exploits a wrapping material that plastically deforms as it expands . . ."); col. 2:21-38; col. 2:59-64; col. 3:7-16; col. 3:27-33 ("The lining can to advantage be made of polymers or compounds thereof."); col. 3:51-62; col. 3:51-62; col. 5:49-54 ("The thread itself in an endoprosthesis of the type illustrated in Fig. 3 can also be wrapped in a coat of medicated and biodegradable wrapping material. . . . The prosthesis can of course alternatively be enclosed in a flexible-tubular coat."); col. 6:50-55; col. 6:59-62; col. 7:16-35; col. 8:4-8; col. 8:19-10:19.

Lambert '246: Abstract ("Thus, a polyurethane coating is applied to a prosthetic article, the coating then swelled . . . so that substantial quantities of biologically active compounds can be incorporated within the interstices of the polymer."); col. 2:15-34; col. 2:40-49; col. 2:53-65; col. 3:55-4:35 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility to as to enable the application of a stable coating onto substrate (i.e. the coating will be able to withstand certain handling, deformation, abrasion,

exposure to various environments, and the like, to which the resulting article will be subjected."); col. 10:45-67; col. 11:34-59; col. 12:15-41.

Bellamkonda '029: Abstract ("A nerve guidance channel for use in regenerating severed nerve is prepared containing a tubular semi-permeable membrane having openings adapted to receive the ends of a severed nerve, and an inner lumen containing the matrix having an adhesive peptide fragment through which the nerve can regenerate."); col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 4:9-14; col. 4:21-39 ("Any suitable hydrogel may be used as the substrate for the bioartificial extracellular matrices of this invention."); col. 4:48-57; col. 5:10-14 ("Several physical properties of the hydrogel matrices of this invention are dependent on gel concentration. Increase in gel concentration may change the gel pore radius, morphology, or its permeability to different molecular weight proteins."); col. 7:13-25; col. 10:28-40 ("Permselective channels with a molecular weight cut-off of 50,000 daltons allowed regeneration of nerves in a mouse sciatic nerve model."); col. 10:41-63; col. 10:64-11:13; col. 12:13-16 ("Preferably the permselective membrane is fabricated to be impermeable to some of these substances so that they are retained in the proximity of the regenerating nerve ends."); col. 12:17-25 ("Briefly, various polymers and polymer blends can be used to manufacture the nerve guidance channel."); col. 12:42-49; col. 19:7-16; col. 23:54-24:55.

Dayton '382: Abstract ("The device comprises a stent which is formed from metal or polymers into a predetermined shape which includes a plurality of holes . . . to provide a desired bending modulus. The stent is then coated with a polymer . . . which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids, with the equilibrium being controlled by charge distribution, concentration and molecular weight of the bioactive substance in relation to the pore size of the polymeric carrier for controlled prolonged release of said bioactive substance."); col. 3:62-4:4:17 ("Among these polymers are polymers having a microporous structure, such as . . . biodegradable polylactic acid polymers, polyglycolic acid polymers . . ."); col. 4:24-33 ("A bioactive substance is preferably admixed in the polymer for elution from the microporous structure of the stent or coating on the stent after implantation. The rate of elution of the bioactive substance is controlled by selecting a pore size for microporous structure . . ."); col. 4: 42-50; col. 4:54-5:3; col. 6:64-7:7 ("The polymer should have a microporous structure with a predetermined pore size."); col. 8:19-33; col. 8:42-59; col. 8:66-9:5; col. 10:1-2.

Burt '036: p. 4:19-33 ("Similarly a wide variety of polymeric carriers may be utilized, representative examples of which include poly(ethylene-vinyl acetate) . . . and copolymers of polylactic acid and polycaprolactone."); p.10:17-25; p.14:9-27 ("As noted above, anti-angiogenic compositions of the present invention comprise an anti-angiogenic factor and a polymeric carrier. In addition to the wide array of anti-angiogenic factors and other compounds discussed above, anti-angiogenic compositions of the present invention may include a wide variety of polymeric carriers, including for example both biodegradable and non-biodegradable compositions."); p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the

composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size."); p.51:1-52:35.

Goldin '568: Col. 1:43-62 ("Release by controlled diffusion may be accomplished by means of containment of the therapeutic agent within a substrate whose small pore size and/or tortuosity of diffusion path thereof limits the diffusion of said agent through the substrate. . . . The therapeutic agent can be incorporated within the diffusion-limiting substrate Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:24-29 ("Microporous membranes for release of proteins by controlled diffusion have been fabricated from ethylene vinyl acetate (EVA), and said membranes have been used in vivo in a manner which demonstrates their therapeutic potential."); col. 5:28-34 (" . . . underlayment material of controlled pore size can be created and used to fabricate a device of optimal porosity . . . and accessibility of the releasable macromolecule to biological material at or beyond the membrane's external surface . . ."); Fig. 1A; col. 11:58-12:14; col. 13:53-65; col. 14:1-28; col. 14:66-15:67; col. 31:57-32:7 ("The device of claim 1 wherein said microporous underlayment comprises a polymer."); col. 32:16-22.

Palmaz '665: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3:47-51 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5: 30-32 ("FIGS. 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon."); Figures 5 and 6.

Palmaz '337: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3:52-56 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5: 19-21; Figures 5 and 6; col. 8: 28-32; col. 9: 24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '762: Col. 10:28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials."); col.3:65-4:2 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 9: 20-25; col. 10: 28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Zaffaroni '254: Abstract ("The wall is formed in at least a part of a microporous material..."); col. 1: 19-23 ("The wall of the device is comprised in at least a part of a microporous material..."); col. 3: 5-10; col. 3: 48-53; col. 4: 47-54 ("Wall 11 is formed of a microporous material the micropores 15 of which contain a drug release rate controlling medium, not shown, permeable to the passage of drug, as by diffusion, or by convection,, or by a concurrent operation of both, but the rate of passage of the drug through the medium in the micropores is lower than the rate of passage of drug through the solid drug carrier."); col. 5: 3-11.

Aebischer: p. 283 (disclosing impermeable polymer layer that restricts passage of treating material).

Dev: p. 273 ("We used a commercially available biomedical grade polyurethane Tecoflex is a biocompatible, flexible, and an elastic membrane-forming polymer.").

Claim 15 [15G] (cont'd): placing the device adjacent to a tissue

Where Found in the Prior References:

Schwartz '823: Abstract ("The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen."); Figs. 6-9, 13, 15; col. 2:37-40 ("In essence, this improvement makes it possible to provide a stent able to support body lumens and conform to curves or irregularities in body lumens."); col. 2:44-54 ("The composite stent of the present invention can be delivered to the site of the occlusion by catheter and expanded conventionally, causing the film to expand or open radially along with the metallic elements of the stent and to be brought into contact with the body lumen. The polymeric film is flexible and preferably an elastic or stretchable film that is capable of conforming to the movement of the metallic stent elements when expanded into contact with a body lumen."); col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:48-54; col. 3:58-col. 4:6; col. 6:49-52 ("As shown in Fig. 13, the stent can be delivered to the body lumen and expanded (e.g. by use of a balloon catheter) into contact with the body lumen."); col. 6:33-37 ("As shown in Fig. 9, with the angioplasty procedure completed, balloon is deflated and withdrawn leaving stent firmly implanted within vessel with the film held in contact with the vessel."); col. 6:62-68 ("Once in the desired location, the stent can be released from the catheter and expanded into contact with the lumen as shown in Fig. 15 where it can conform to the curvature of the body lumen. The

flexible film is able to form folds which allow the stent elements to readily adapt to the curvature of the body lumen.").

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14 ("The present invention satisfies this need by providing a separate sleeve to encompass the stent and serve as a local drug delivery device to prevent thrombosis."); col. 4:53-55 ("The present invention satisfies this need by providing a separate sleeve to encompass a stent to locally administer drugs to prevent restenosis."); col. 4:58-68 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. . . . Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 5:26-29; col. 6:49-55 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface); col. 8:8-22; col. 8:58-60 ("The films were placed to line the circumference of a 2 cm length of ePTFE grafts, over which a 2 cm long stent was deployed."); col. 9:12-16 ("In addition, polymer-drug films which prevent thrombosis in the baboon and pig AV shunt system can be studied following stent-film placement in carotid, superficial femoral and coronary arteries following balloon injury of those vessels."); col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film

capable of carrying and releasing therapeutic drugs."); col. 1:12-20 ("Stents are typically implanted within a vessel in a contracted state and expanded when in place in the vessel in order to maintain patency of the vessel to allow fluid flow through the vessel. Ideally, the implantation of such stents is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:50-56 ("The stent can be used in coronary arteries or any other part of the vasculature or other body lumen where mechanical opening force is necessary or desirable to keep the vessel open or to maintain the stent flush against the lumen wall, and where an anti-restenosis, anti-proliferative or other types of therapeutic drug or agent is to be simultaneously positioned and diffused."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 2:23-33; col. 5:15-17; col. 7:56-62; col. 9:63-67 ("The deployment of the stent can also be improved by . . . decreasing friction between the vessel or lumen wall and the stent."); col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:52-54 ("The invention provides prostheses which may be inserted into a lumen of a body and fixed to the lumen wall adjacent an area needing treatment."); col. 1:63-66 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery."); col. 2:7-9 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:25-27 ("The current invention contemplates the usage of any prosthesis which elutes drugs locally to treat a lumen in need of repair."); col. 6:36-38; col. 6:56-58 ("The stent shown in Figs. 2 and 4 is a metallic malleable design which may be forced against a lumen wall by a balloon catheter which fixes it into position."); col. 6:64-67 ("The variations of design shown in the embodiments of Figs. 1 and 2 show that the prosthesis of the invention must be secured against a lumen wall and must carry a drug-eluting polymer."); col. 9:67-10:3 ("By including a metal stent within the lumen of the polymeric prosthesis, the polymeric prosthesis is effectively held against the wall of the body lumen by the strength of the metal stent."); col. 10:23-38 ("The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen. This will bring the bioabsorbable element into supporting contact with a body

lumen at an interior position of the body lumen to be treated and will position the bioabsorbable element to deliver drugs to the body lumen. Following the expansion of the stents into luminal contact, the balloon (if the expansion device is a balloon) can be deflated which allows the luminal flow to be restored."); col. 10:46-59; col. 11:10-13; col. 11:17-20; col. 11:50-53 ((b) a body including a plurality of support elements forming an open-ended, radially expandable, self-supporting tubular structuring having an interior surface and an exterior surface."); col. 12:1-15.

Berg '354: Page 2:14-18 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen. Examples of stents which have been successfully applied over a PTCA balloon and radially expanded at the same time as the balloon expansion of an affected artery include the stents disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) which are incorporated herein by reference in their entirety."); p. 2:34-36 ("Metal stents such as those disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) could be suitable for drug delivery in that they are capable of maintaining intimate contact between a substance applied to the outer surface of the stent and the tissues of the vessel to be treated."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:16-18 ("In operation, the stent made according to the present invention can deliver drugs to a body lumen by introducing the stent transluminally into a selected portion of the body lumen and radially expanding the stent into contact with the body lumen.").

Buscemi '450: Col. 3:14-15 ("The stent strengthens an area of the vessel that is in contact with the stent."); col. 3:21-25 ("The tubular main body includes an outer surface and inner surface. The outer surface of the main body faces an inner surface wall of the vessel. The inner surface of the stent faces a stream flowing through the lumen as shown in cross section in Fig. 2."); col. 4:61-64 ("The stent is secured by releasing the stent from compression so that the stent can radially spring out to abut against the inner surface wall of the vessel."); col. 6:49-52; col. 7:27-29; col. 8:9-11.

Ding '536: Col. 5:38-40 ("Surface material should minimize tissue rejection and tissue inflammation and permit encapsulation by tissue adjacent the stent implantation site.").

Dinh '227: Col. 1:32-35 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing mechanical support for the lumen."); col. 8:20-23 ("The term "stent" herein means any device which when placed into contact with a site in the wall of a lumen to be treated, will also place fibrin at the lumen wall and retain it at the lumen wall."); col. 8:37-43; col. 9:18-24 ("The stent is then delivered through the body lumen on the catheter to the treatment site where the stent is released from the catheter to allow it to expand into contact with the lumen wall.").

Domb '055: Abstract ("Preferred embodiments include catheters, tubes, and implants that abut tissue following implantation into the body . . ."); col. 4:25-32; col. 5:27-33; col. 5:49-54;

col. 5:63-6:1 ("Coating that part of the tube, which is in contact with the mucosa, with the drug-loaded polymer provides a sustained release of steroids and antibiotics locally and at high concentration in the area which is critically affected, achieving the same effect as the systemic administration of the drugs without their side effects, throughout the duration of the intubation."); col. 6:8-18; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages.").

Kowligi '782: Abstract; col. 1:18-41; Figs. 2, 3; col. 10:18-67.

Hunter '981: Col. 4:24-38; col. 5:1-6; col. 16:31-56; col. 22:3-7; col. 22:54-58; col. 23:6-13 ("[M]ethods are provided for expanding the lumen of a body passageway, comprising inserting a stent into the passageway, the stent having a generally tubular structure, the surface of the structure being coated with an anti-angiogenic composition . . . such that the passageway is expanded."); col. 23:30-31; col. 23:46-51; col. 24:45-51; col. 24:66-25:5; col. 25:24-29; col. 25:48-54; col. 52:4-8 ("This film is designed to be placed on exposed tissue so that any encapsulated drug is released from the polymer over a long period of time at the tissue site."); 86:56-59; col. 87:11-22; col. 88:19-26.

Lambert '922: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion."); col. 3:54-61; col. 8:1-6.

Lambert '308: Page 3:24-27 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion.").

Myler '563: Col. 3:34-37 ("Stent 10 is illustrated in its expanded position at a treatment location adjacent vascular wall in an artery, in accordance with one aspect of the present invention."); col. 4:53-56 ("The exterior surface of the envelope which will contact the arterial wall is optionally made porous to enable the release of drugs from the envelope and/or stent to the treatment site."); col. 10:12-14 ("The balloon is inflated, thereby expanding the stent radially outwardly until it contacts either a previously dilated, or presently stenosed wall."); col. 10:56-61; col. 11:63-65 ("Once the stent has been positioned at the treatment site, axial elongating tension is released, and it is permitted to radially expand against the lumen wall."); col. 13:15-17 ("The exterior coating which will contact the arterial wall is optionally made porous to enable the release of drugs to the treatment site.").

Palmaz '417: col. 4:25-37 (" . . . expanding a portion of the catheter associated with the prostheses to force at least one of the prostheses radially outward into contact with the body passageway . . .").

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); Figs. 1 and 2; col. 9:18-10:3.

Strecker '746: Figs. 7 & 8.

Schiraldi '243: Col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Valentini '029: Abstract ("In particular, tubular channels which have a smooth inner surface and longitudinally oriented trabeculae result in significantly larger regenerated nerve cables and higher numbers of regenerated myelinated axons."); Figure 3; col. 2:32-35 ("Medical devices employing such selectively permeable materials, particularly semipermeable tubular devices having smooth inner skins, are disclosed for use in regenerating nerves."); col. 2:58-3:14; col. 5:33-41; col. 6:14-24.

Bawa '279: Col. 6:40-44; col. 12:29-34.

Wood '066: Col. 2:67-3:32 ("The object of this invention is to provide means for delivery effective dosages of therapeutic agents to sites of trauma such as wounds, thermal or chemical burns, ulcers, lesions, or surgical sites.").

Aebischer '486: Fig. 1.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:63-2:2; col. 2:21-32; col. 2:33-38; col. 2:39-46; col. 3:63-4:31 ("It can be of advantage for the lining to be of several layers, each impregnated with different medications. . . . It has also been demonstrated practical for the inner layer of the lining to be impregnated with antithrombotics

and the outer with antiproliferatives and/or other medicational substances.); Fig. 4; col. 5:18-20 ("Fig. 4 is a view similar to that of Fig. 2 of an endoprosthesis with a multiple-layer lining and with its ends coated with medication,"); col. 5:34-41 ("The endoprosthesis . . . is completely enclosed in an inner lining component and an outer lining component."); Fig. 7; col. 6:30-44 ("The endoprosthesis 40 in the embodiment illustrated in Fig. 7 comprises a lining 42 and 43 in the form of a double walled sleeve. The outer lining component 43 of the in-place and expanded stent rests against the inner surface 46 of the blood vessel. Inner lining component 42 rests against the stent."); col. 7:16-35; col. 7:48-65; col. 8:19-10:19.

Lambert '246: Col. 2:29-31 ("When the target tissue is in contact with the polyurethane, the biologically active compound distributes in the tissue by passive diffusion.").

Bellamkonda '029: Fig. 6.

Dayton '382: Abstract ("The stent is then coated with a polymer or is formed from a polymer which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids . . ."); col. 4:4-10; col. 6:64-7:7; col. 8:18-19 ("a polymer forming the exterior surface of said stent for operative contact with said tissue . . .").

Burt '036: p.14:9-27; p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size.").

Goldin '568: Figs. 5A-5F; col. 9:7-12 (" . . . a substance that, when implanted in or juxtaposed against a living body . . ."); col. 22:46-23:3.

Palmaz '665: Col.3: 55-65 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into the body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded..."); col. 5:9-13; Figure 4; col. 8:9-14.

Palmaz '762: Col. 4: 14-19 (...expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway..."); col. 4: 53-56; col. 5: 43-45; col. 9: 1-6.

Palmaz '337: Col. 3:60-4:2 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into a body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded, whereby the intraluminal graft prevents the body passageway from collapsing and decreasing the size of the expanded lumen."); col. 4: 36-40; col. 5: 32-34; col. 7: 28-36; col. 8: 17-22.

Zaffaroni '254: Col. 7: 18-25 ("Secondly, the carrier contacts and bathes the inner surface of wall 11 for facilitating drug transfer from the carrier to the wall so that drug molecules can dissolve in a diffusive medium in the microporous wall and migrate through it to the outer surface thereof.").

Aebischer: Fig. 2A (disclosing one major surface facing the nerve stumps).

Dev: Abstract ("Polymer-coated stents could be used for local drug delivery to the vessel wall."); p. 273 ("... to compare these two drugs with respect to kinetics of their delivery to the arterial wall with the stent in place ...").

Claim 15 [15H] (cont'd): whereby the placed device permits directional presentation of the at least one treating material.

Where Found in the Prior References:

Peterson '166: Abstract ("A time-release chemical delivery system in which a bioactive compound is attached to a polymeric biodegradable carrier by a hydrolysable bond is disclosed. The bioactive compound can either be bound directly to the polymer or be attached to the polymer via a spacer group."); col. 1:28-38; col. 1:51-55 ("Another object of the instant invention is to provide a bioactive compound via covalent bonding to a polymeric backbone so that upon hydrolysis of said covalent bond said bioactive compound is released in active, unmodified form."); col. 1:60-62; col. 1:67-col. 2:2; col. 2:40-50 ("A further requirement of the polymeric carriers are that they contain a pendant group to which a reactive compound may be directly attached by a hydrolyzable bond or to which a spacer unit may be attached with the reactive compound attached to the spacer unit by a hydrolysable bond. Typically, the space [sic] unit will also be attached to the polymeric carrier by a hydrolyzable bond."); col. 2:51-60; col. 3:67-4:2; col. 4:3-7 ("The use of a spacer group may also provide desirable changes in drug release rate by allowing ease of hydrolysis of the drug."); col. 4:8-19; col. 4:56-5:2; col. 6:28-55; col. 6:55-62 ("Since the proximity of the reactive carboxyl group to the polymer backbone may interfere with the addition of a bioactive compound, especially a large molecule, and with the subsequent hydrolysis of a covalent bond formed by such condensation reaction, the use of a spacer group, preferably linear in nature, may be preferred in this invention."); col. 6:65-col.7:28 ("To be effective as hydrolysable carriers the polymers of this invention must have pendant reactive sites to which a bioactive compound may be attached. . . . These functional groups may react with functional groups of the bioactive compound to form a hydrolysable bond. The hydrolysable bond may be direct between the pendant group of the polymer and the reactive compound or it may be first reacted with a spacer unit which contains a similar reactive functional group. . . . The reactivity of the reactive sites is also affected by the distance of the reactive site from the backbone of the polymer."); col. 7:32-53 ("Spacer groups may be utilized in the practice of the instant invention to provide a hydrolysable unit which spaces the reactive compound further from the carrier backbone. As indicated hereinabove, the polymeric units may

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contain long pendant chains which place the reactive site on the pendant group further away from the carrier backbone. . . ."); col. 7:57-62 ("Bioactive compounds useful in this invention are those which contain a group which may react to form a bond with a pendant group or a spacer group. The bond is preferably hydrolysable and in particular are esters, including sulfates or phosphate esters, amides, carbonates and urethane bonds."); col.8:25-28 ("The reactive compound which is released over a period of time in the instant invention may be one which has a pharmacological affect upon the host, for example, a contraceptive drug in an animal."); col. 8:34-49 ("Factors which affect the release rate and the rate of absorption into the body of the host include . . . the composition of the polymer backbone, the length and character of the spacer groups and the character of the pendant groups The spacing of the bulky drug or chemically reacted compound from the polymer also affects the rate of release."); col. 11:25-12:4 (" . . . a bioactive compound chemically attached to said carrier by a hydrolysable bond, said bioactive compound containing a group which reacts with a group on the biodegradable polymer to form a hydrolysable bond and being effective in small dosages to produce a biological effect within said host upon release into the host by hydrolysis of the hydrolyzable bond."); col. 12:14-24 ("The chemical delivery system of claim 1 wherein said bioactive compound is indirectly coupled to said carrier by a hydrolyzable bond to a spacer compound. . . . The chemical delivery system of claim 7 wherein said spacer compound is coupled to said bioactive compound by a hydrolyzable bond."); col. 12:28-30.

Schwartz '823: Col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:64-4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof."); col. 7:1-4 ("In yet another aspect of the present invention, various therapeutic substances can be incorporated in or applied to the polymeric film to provide such substances to the blood or to the lumen wall."); col. 7:14-25 ("Application of the therapeutic substance to the film can include applying it on the surface of the film or incorporating it into the film as it is made. For example, microcapsules can be used to carry the therapeutic substance either in or on the film and to provide timed-release of the substance to the blood, or to the blood vessel or both."); col. 7:25-34 ("Microcapsules containing one type of therapeutic substance could be provided on one side of the film and microcapsules containing another therapeutic substance could be incorporated on the other side of the film, thus providing a stent according to the present invention which provides one type of therapeutic substance (e.g. an anti-thrombotic drug) to the blood and another type of therapeutic substance (e.g. an antiproliferative drug) to the vessel wall."); col.8:5-11 ("The resulting stent has microcapsules containing one therapeutic substance on the inside (and able to contact blood once implanted in a blood vessel) and microcapsules containing a second therapeutic substance on the outside (and able to contact the vessel wall when implanted in contact with the vessel wall)."); col. 8:46-47.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 4:12-14; col. 4:53-55; col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-33; col. 5:34-6:23 ("Many polymers can also be used to make the sheath, including biodegradable and non-degradable polymers. The polymer is selected depending on the drug selected, the polymer's compatibility with a subject and the ultimate pharmacologic effect desired. . . . Another alternative would be to use a polymer which is biodegradable over a short period of time. Naturally, the opposite characteristics would be selected for a desired prolonged release. The characteristics of the particular polymer for these purposes is well known to the skilled artisans or can be determined by reference to standard references . . ."); col. 6:39-41 ("The initial prototype is a sleeve of polymer, either degradable or non-degradable, that covers the entire stent (Fig. 3)"); col. 6:64-68 ("The duration of drug delivery is accurately predicted by the characteristics of the polymer. For example, if the polymer is biodegradable, then the rate and duration of drug delivery is related to the thickness of the polymer."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface."); col. 8:23-54; col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33 ("In combination, a hollow tubular stent having a predetermined length and a separate sheath removably encompassing at least a portion of said hollow tubular stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug."); col. 11:11-12 ("14. The sheath of claim 1, wherein the polymer is biodegradable."); col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); col. 1:7-10 ("This invention relates generally to expandable intraluminal vascular grafts, generally

referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 5:4-9 ("The primary function of the sheet of polymeric material is to deliver therapeutic agents or drugs to help prevent thrombosis and/or restenosis."); col. 5:49-6:25 ("The polymeric material is preferably bioabsorbable, and is preferably loaded or coated with a therapeutic agent or drug . . ."); col. 7:23-25; col. 10:12-30.

Wolff '208: Abstract ("A prosthesis for insertion into a lumen to limit restenosis of the lumen. The prosthesis carries restenosis-limiting drugs which elute after the device is positioned in the lumen."); col. 1:11-13 ("This invention related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis."); col. 1:63-2:6 ("The prostheses of the invention include at least one drug which will release from the device at a controlled rate to supply the drug where needed without the overkill of systemic delivery. The prostheses may be completely biodegradable or may be bioabsorbable in whole or incorporated into the lumen wall as a result of tissue overgrowth, i.e. endothelialization. Alternatively, the prostheses may be biostable in which case the drug is diffused out from the biostable materials in which it is incorporated."); col. 2:28-30 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 2:55-58; Fig. 5; col. 6:5-10 ("When drugs are delivered locally via the prosthesis of the invention, they may be at therapeutic levels at the diseased site while at the lower limits of detectability in the bloodstream. So little drug is required for effective local treatment of a lumen that the drug may not be detectable in blood samples."); col. 6:36-38; col. 6:59-63 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously. the polymer may be biostable or bioabsorbable. If biostable, the drug would diffuse out of the polymer."); col. 6:64-67; col. 7:19-23; col. 7:53-55 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 7:59-8:25; col. 8:26-31 ("The compound which is preferred is a polyphosphate ester. Polyphosphate ester is a compound such as that disclosed in U.S. Pat. Nos. 5,176,907; 5,194,581; and 5,656,765 issued to Leong which are incorporated herein by reference. Similar to polyanhydrides, polyphosphate ester is being researched for the sole purpose of drug delivery."); col. 8:40-9:22 ("It is the hydrolytic instability of the phosphorous ester bond which makes this polymer attractive for controlled drug release

applications. A wide range of controllable degradation rates can be obtained by adjusting the hydrophobicities of the backbones of the backbones of the polymers and yet assure biodegradability. The functional side groups allow for the chemical linkage of drug molecules to the polymer."); col. 12:12-15.

Berg '354: Page 2:27-31 ("Other methods of providing therapeutic substances to the vascular wall include simple heparin-coated metallic stents, whereby a heparin coating is ionically or covalently bonded to the stent. Still other methods of providing therapeutic substances to the vascular wall by means of stents have also been proposed such as in US-A-5102417 (Palmaz), WO-91/12779 "Intraluminal Drug Eluting Prosthesis" and WO-90/133332 "Stent With Sustained Drug Delivery".); p. 3:7-9; p. 3:22-23 ("It also provides a drug-containing stent which allows for a sustained release of the drug to vascular tissue."); p. 4:25-27 ("The ratio of therapeutic substance to polymer in the solution will depend on the efficacy of the polymer in securing the therapeutic substance onto the stent and the rate at which the coating is to release the therapeutic substance to the tissue of the blood vessel."); p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Abstract ("A stent made of biodegradable material includes a drug that is released at a rate controlled by the rate of degradation of the biodegradable material."); col. 1:61-63; col. 2:6-8 ("The mechanism of biodegradation is described as hydrolysis resulting in degradable products excreted in urine or reabsorbed into tissues."); col. 2:49-52 ("Also desired are stents which can deliver drugs or biologically active agents at a controlled rate to blood passing through the vessel lumen as well as to the vessel wall."); col. 2:56-61 ("The biodegradable stent is made from at least one biodegradable material that is also biocompatible and includes a drug which is released into the lumen of the vessel at a rate controlled by the rate of degradation of the biodegradable material."); col. 3:11-12 ("The rate of drug release is controlled by the rate of degradation of the biodegradable materials."); col. 3:53-55; col. 4:12-14; col. 4:23-25 ("The present invention further includes a main body having more than one biodegradable interior film layer."); col. 4:65-5:5 "In the most preferred embodiment, the biodegradable stent of the present invention is made of biodegradable materials that are also biocompatible. By biodegradable is meant that a material will undergo breakdown or decomposition into harmless compounds as part of a normal biological process"); col. 5:11-19 ("Suitable biodegradable materials for the main body of the stent of the present invention include polylactic acid, polyglycolic acid (PGA), collagen or other connective proteins or natural materials, polycaprolactone, hyaluric acid, adhesive proteins, co-polymers of these materials as well as composites and combinations thereof and combinations of other biodegradable polymers."); col. 5:21-37; col. 5:38-45 ("Consequently, the presence of different biodegradable materials in the stent permits the stent to degrade in a predictable, orchestrated fashion."); col. 5:46-54 ("As the stent biodegrades, drugs are administered to the surrounding tissue or to the blood stream. Thus, the rate of drug release is controlled by the rate of degradation of the biodegradable materials."); col. 6:3-8; col. 6:45-59; col. 7:2-9; col. 7:32-8:9; col. 8:27-30.

Ding '536: Abstract ("In one embodiment, the surface is provided with sites of high electronegativity species by coating with fluorosilicone which aid in controlled elution,

particularly the initial release rate, and reduce thrombogenic activity."); col. 2:38-42 ("Such an approach is described by Winters, et al., in U.S. Pat. Nos. 5,182,317; 5,262,451 and 5,338,770 in which the amine functional groups of the active material are covalently bonded using a polyethylene oxide (PEO) on a siloxane surface."); col. 2:43-46 ("Another approach is described in U.S. Pat. No. 4,613,665 to Larm in which heparin is chemically covalently bound to impart a non-thrombogenic surface to the material."); col. 3:19-27 ("Accordingly, it is a primary object of the present invention to provide a coating and process for coating a stent to be used as a deployed stent prosthesis, the coating being capable of effective controlled long-term delivery of biologically active materials. Another object of the invention is to provide a coating and process for coating a stent prostheses using a biostable hydrophobic elastomer in which biologically active species are incorporated within a coating."); col. 6:16-27 ("The mechanism of incorporation of the biologically active species into the surface coating and egress mechanism depend both on the nature of the surface coating polymer and the material to be incorporated. The mechanism of release also depends on the mode of incorporation. The material may elute via interparticle paths or be administered via transport or diffusion through the encapsulating material itself."); col. 6:28-34; col. 6:35-48; col. 10:35-40 ("In addition, because of the negative charges on the heparin itself, the electro-negativity of the fluorosilicone topcoat may be, at least in part, responsible for the modified heparin release kinetic profile."); col. 12:62-67 ("Whereas the polymer of the coating may be any biostable elastomeric material capable of being adhered to the stent material as a thin layer, hydrophobic materials are preferred because it has been found that the release of the biologically active species can generally be more predictably controlled with such materials. Preferred materials include silicone rubber elastomers and biostable polyurethanes specifically.").

Dinh '227: Col. 2:26-32; col. 3:10-14; col. 5:53-55 ("Suitable polymers could also be biodegradable polymers such as polyphosphate ester, polyhydroxybutyrate valerate, polyhydroxybutyrate-co-hydroxyvalerate and the like."); col. 6:13-22; col. 6:32-50; col. 6:50-56; col. 7:10-13 ("The adhesion of the coating and the rate at which the drug is delivered can be controlled by the selection of an appropriate bioabsorbable or biostable polymer and by the ratio of drug to polymer in the solution."); col. 7:13-23; col. 7:30-44; col. 7:45-51 ("The polymer used can be bioabsorbable or biostable polymer. Suitable bioabsorbable polymers include poly(L-lactic acid), poly(lactide-co-glycolide) and poly(hydroxybutyrate-co-valerate). Suitable biostable polymers include silicones, polyurethanes, polyesters, vinyl homopolymers and copolymers, acrylate homopolymers and copolymers, polyethers and cellulotics."); col. 9:17-18; col. 12:38-50.

[Domb '055: Abstract ("Preferred polymeric coatings are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); col. 3:54-62 ("In the preferred embodiments, these have utilized bioerodible polymers as the matrix for the drug to be released, usually as a function of diffusion and erosion of the polymer. The advantage of these drug delivery systems is that they provide a sustained/continuous release of drugs locally and at a relatively high concentration in areas of the body, without systemic side-effects, throughout the duration of their release."); col. 4:11-13 ("It is a further object of the present invention to provide medical devices having prolonged low-dose, localized release of anti-microbial and anti-inflammatory agents."); col. 4:33-36; col. 5:27-33; col. 5:41-45 ("The drug-loaded polymer provides a sustained release

of steroids and antibiotics locally and at a relatively high concentration in that area which is critically affected, without the side-effects of the systemic administration of the same drugs, throughout the duration of intubation."); col. 5:49-54; col. 5:60-6:1 ("An esophageal silicone stent coated with a film of polymer can be used to provide a site-specific controlled release of corticosteroids and antibiotics."); col. 6:3-7; col. 6:24-26 ("Examples of suitable polymers include ethylene vinyl acetate, polyurethane, silicones, hydrogels, polyurethane, and polyvinyl chloride."); col. 6:42-45 ("Release is a function of diffusion of the agent from the polymeric matrix, and varies by size, concentration and solubility of the agent, as well as by thickness and chemical composition of the polymeric matrix."); col. 7:10-20; col. 7:25-29; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 11:36-38 ("The medical device of claim 1, wherein the polymer is selected from the group consisting of polyurethane, ethylene vinyl acetate, silicones, hydrogels, and polyvinyl chloride."); col. 11:39-44; col. 12:1-7; col. 12:11-22; col. 12:23-25; col. 12:26-31; col. 12:32-42.

Fox '096: Abstract ("A method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers, and antimicrobial agents . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 3:55-67 ("The polymeric coating agent component of the coating vehicle of the present invention is selected from the group consisting of biomedical polyurethanes, biomedical silicones, biodegradable polymers and combinations thereof."); col. 4:30-5:35; col. 7:22-25; col. 7:28-32; col. 11:34-48 ("Suitable biodegradable polymers include the homopolymers poly(glycolic acid), poly(D-lactic acid), poly(D,L-lactic acid), poly(D,L-ethyl-glycolic acid), poly(dimethylglycolic acid), poly(D,L-methylethylglycolic acid), and poly(E-caprolactone), as well as biodegradable polyhydroxy butyric acid and mixtures thereof. A preferred biodegradable polymer is polylactic acid (PLA)."); col. 11:51-56 ("The biodegradable polymer modulates the rate of release of antimicrobial drugs."); Table IV; col. 12:24-41 ("Suitable biomedical poly(lactic) polymers include the poly(L-lactide), poly(D-lactide) and the poly (D-L-lactic acid). . . . The poly(lactic acid) polymers are bioerodible, and while they can be used alone, it is preferred that they be combined with either a biomedical polyurethane or a biomedical silicone."); col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages."); col.

18:19-25; col. 20:54-58; col. 28:13-18; col. 29:38-40 (Adding a biodegradable material containing anti-microbial agents to the adhesive to provide controlled-release through degradation."); col. 36:21-31; col. 36:47-51; col. 36:65-37:7; col. 37:29-31; col. 37:56-57; col. 37:63-65; col. 37:66-38:9; col. 38:24-30; col. 39:39-41; col. 40:33-34; col. 40:39-42.

Hunter '981: Abstract; col. 3:42-61 ("A wide variety of molecules may be utilized within the scope of the present invention as anti-angiogenic factors, including for example Anti-Invasive Factor, retinoic acids and their derivatives, paclitaxel including analogues and derivatives thereof, Suramin, Tissue Inhibitor of Metalloproteinase-1, Tissue Inhibitor-1 and Plasminogen Activator Inhibitor-2, and lighter "d group" transition metals. Similarly, a wide variety of polymeric carriers may be utilized, representative examples of which include poly (ethylene-vinyl acetate) (40% cross-linked), poly (D,L-lactic acid) oligomers and polymers, poly (L-lactic acid) oligomers and polymers, poly(glycolic acid), copolymers of lactic acid and glycolic acid, poly(caprolactone), poly(valerolactone), poly(anhydrides), copolymers of poly(caprolactone) or poly(lactic acid) with polyethylene glycol, and blends thereof."); col. 5:27-32; col. 12:23-35 ("As noted above, the present invention provides compositions comprising an anti-angiogenic factor, and a polymeric carrier."); col. 16:31-56 ("Anti-angiogenic compositions of the present invention are provided in a wide variety of polymeric carriers, including for example both biodegradable and non-biodegradable compositions. Representative examples of biodegradable compositions include albumin, gelatin, starch, cellulose, dextrans, polysaccharides, fibrinogen, poly (D,L lactide), poly (D,L-lactide-co-glycolide), poly (glycolide), poly (hydroxybutyrate), poly (alkylcarbonate) and poly (orthoesters) Representative examples of nondegradable polymers include EVA copolymers, siliconerubber and poly (methylmethacrylate). Particularly preferred polymeric carriers include poly (ethylene-vinyl acetate)(40% cross-linked), poly(D,L-lactic acid) oligomers and polymers, poly (L-lactic acid) oligomers and polymers, poly (glycolic acid), copolymers of lactic acid and glycolic acid, poly (caprolactone), poly (valerolactone), polyanhydrides, copolymers of poly (caprolactone) or poly (lactic acid) with polyethylene glycol and blends thereof."); col. 16:31-56; col. 16:66-17:6 ("Anti-angiogenic factors may be linked by occlusion in the matrices of the polymer, bound by covalent linkages, or encapsulated in microcapsules. Within certain preferred embodiments of the invention, anti-angiogenic compositions are provided in non-capsular formulations such as microspheres . . . pastes, threads of various size, films and sprays."); col. 17:7-26; col. 17:41-43 ("Anti-angiogenic compositions may also be prepared, given the disclosure provided herein, for a variety of other applications."); col. 18:15-49 ("Within further aspects of the present invention, polymeric carriers are provided which are adapted to contain and release a hydrophobic compound, the carrier containing the hydrophobic compound in combination with a carbohydrate, protein or polypeptide. Within certain embodiments, the polymeric carrier contains or comprises regions, pockets, or granules of one or more hydrophobic compounds."); col. 47:58-49:7; col. 56:45-57; col. 57:17-31; col. 59:65-60:48; col. 59: 32-59 ("Poly(e-caprolactone) is an aliphatic polyester which can be degraded by hydrolysis under physiological conditions and it is non-toxic and tissue compatible."); col. 69:19-62; col. 77:43-55 ("The release of paclitaxel, in this case, is dominated by polymer degradation."); col. 78:58-79:5 ("Although not specifically set forth above, a wide variety of other polymeric carriers may be manufactured, including for example . . ."); col. 84:62-86:24; col. 86:60-67.

Kinsella '608: Col. 11:18-24 ("Drug delivery systems that can be valuable include drug-impregnated polymer-coated metallic stents [and] biodegradable drug-eluting polymer stents . . .").

Kowligi '782: Col. 4:16-27 ("In regard to elastomeric coating 38 shown in Fig. 2, such elastomeric coating is selected to be a biocompatible elastomers and may be selected from the group consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 10:18-27; col. 10:28-32 ("The implantable vascular graft recited by claim 1 wherein said elastomers is selected from the group of elastomers consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 10:43-50; col. 10:60-67.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 1:46-55 ("Release of heparin from intravascular catheters in quantities sufficient to decrease thrombosis on the catheter has been achieved by either covalently bonding a charged molecule to a polymer or incorporating a large nonmobile charged molecule on the surface of the polymer . . ."); col. 1:62-65; col. 2:16-35; col. 2:40-50 ("In accordance with the present invention, there is provided a method for preparing a system suitable for localized delivery of biologically active compounds to a subject."); col. 2:55-67; col. 3:8-12; col. 3:29-49; col. 4:10-17; col. 7:29-32; col. 7:38-41; col. 8:62-9:19 ("Adventitia overlying the stent contained 360 times the concentration of forskolin in the blood and 305 times the concentration of forskolin in the contralateral artery. . . . In a similar model, etretinate, a retinoic acid analog, develops concentrations in the media of 250 ng/mg tissue at 24 hours. At 24 hours, this concentration was over 2000 times the concentration in the blood."); col. 9:31-37 ("These data demonstrate that a polyurethane coated nitinol stent is capable of delivering a lipophilic drug in high local concentration in the vessel wall. The large 450 fold differential of local tissue levels of forskolin over blood levels reflects the capability of this delivery system to provide high local concentration and potentially higher efficacy, with lower risk of systemic side effects."); col. 12:21-22 ("The method in accordance with claim 1, wherein the biologically active compound is a lipophilic compound."); col. 12:27-30 ("The method in accordance with claim 1, wherein the biologically active compound is a hydrophilic compound, said method further comprising linking the hydrophilic compound to a lipophilic carrier.").

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p. 2:10-19 ("Release of heparin from intravascular catheters in quantities sufficient to decrease thrombosis on the catheter has been achieved by either covalently bonding a charged molecule to a polymer or incorporating a large nonmobile charged molecule on the surface of the polymer . . ."); p. 2:25-30; p. 3:10-31 ("Upon long-term exposure of a prosthetic article to physiological

conditions, the biologically active compound is slowly released from the treated polymer."); p. 4:2-12; p. 4:17-31; p. 15:25-16:14 ("Adventitia overlying the stent contained 360 times the concentration of forskolin in the blood and 305 times the concentration of forskolin in the contralateral artery. . . . In a similar model, etretinate, a retinoic acid analog, develops concentrations in the media of 250 ng/mg tissue at 24 hours. At 24 hours, this concentration was over 2000 times the concentration in the blood."); p.16:27-34 ("These data demonstrate that a polyurethane coated nitinol stent is capable of delivering a lipophilic drug in high local concentration in the vessel wall. The large 450 fold differential of local tissue levels of forskolin over blood levels reflects the capability of this delivery system to provide high local concentration and potentially higher efficacy, with lower risk of systemic side effects."); claim 14 ("The method in accordance with claim 1, wherein the biologically active compound is a lipophilic compound."); claim 16 ("The method in accordance with claim 1, wherein the biologically active compound is a hydrophilic compound, said method further comprising linking the hydrophilic compound to a lipophilic carrier."); claim 26.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8; p. 1:56-58.

Mitchell '711: Col. 6:24-28 ("Suitable solid carrier include, for example, calcium phosphate, magnesium stearate, talc, sugars, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, sodium carboxymethyl cellulose, polyvinylpyrrolidone, low melting waxes and ion exchange resins.").

Morris '781: Col. 10:50-54 ("Suitable solid carriers include, for example, calcium phosphate, magnesium stearate, talc, sugars, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, sodium carboxymethyl cellulose, polyvinylpyrrolidone, low melting waxes and ion exchange resins.").

Morris '182: Page 6:54-56 ("Suitable solid carriers include, for example, calcium phosphate, magnesium stearate, talc, sugars, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, sodium carboxymethyl cellulose, polyvinylpyrrolidone, low melting waxes and ion exchange resins.").

Myler '563: Col. 4:57-59; col. 4:60-67 ("[T]he stent can be provided with a solid drug carrier such as an impregnated porous solid wall or sponge for timed drug delivery."); col. 5:39-41 ("For the above reasons, even the expanded pores for drug delivery should be small enough to maximize or prevent cell penetration, but large enough for drug delivery."); col. 13:15-18 ("The exterior coating which will contact the arterial wall is optionally made porous to enable the release of drugs to the treatment site.").

Palmaz '417: Col. 11:8-11; col. 11:26-34 ("Examples of biologically compatible coatings would include coatings made of absorbable polymers such as those used to manufacture absorbable sutures. Such absorbable polymers include polyglycoides, polyacoides, and copolymers thereof. Such absorbable polymers could also contain various types of drugs, whereby as the coating is absorbed, or dissolves, the drug would be slowly released into the body passageway.").

Tice '330: Col. 3:20-33 ("A preferred group of polymeric wall forming materials includes those which are biodegradable such as aliphatic polyesters including polylactide, polyglycolide, polycaprolactone and copolymers thereof."); col. 8:38-51.

Thies '317: Abstract ("The capsules provide controlled release of the active agent over a prolonged period of time."); col.1:15-19 ("The art of encapsulation has developed various processes and methods for individually coating particular matter for purposes of controlled release or metering out of an active agent over a prolonged period."); col. 2:26-38; col. 2:43-47; col. 2: 48-51; col. 3:41-4:2; col. 6:35-39 ("Therefore, the presence of a soluble alkali metal silicate in the interior of the capsule causes much of the capsule coating material to simply disappear upon immersion in water thereby causing accelerated release of the active agent."); col. 7:36-11:68; col. 12:10-40; col. 13:4-14:3.

Tice '840: Col. 2:32-34; col. 2:38-55 ("The polymeric matrix material of the microparticles of the present invention must be a biocompatible and biodegradable polymeric material. . . . Suitable examples of polymeric matrix materials include poly (glycolic acid), poly-d,l-lactic acid, copolymers thereof, copolyoxalates, polycaprolactone, poly (lactic acid-caprolactone), and the like."); col. 2:56-3:8 ("The molecular weight of a polymer is also important from the point of view that molecular weight influences the biodegradation rate of the polymer. The drug can also be released from the microparticles as the polymeric excipient bioerodes. By an appropriate selection of polymeric materials a microparticle formulation can be made such that the resulting microparticles exhibit both diffusional release and biodegradation release properties."); col. 10:56-11:15; col. 12:6-9.

Tice '025: Col. 2:32-34; col. 2:38-55 ("The polymeric matrix material of the microparticles of the present invention must be a biocompatible and biodegradable polymeric material. . . . Suitable examples of polymeric matrix materials include poly (glycolic acid), poly-d,l-lactic acid, copolymers thereof, copolyoxalates, polycaprolactone, poly (lactic acid-caprolactone), and the like."); col. 2:56-3:8 ("The molecular weight of a polymer is also important from the point of view that molecular weight influences the biodegradation rate of the polymer. The drug can also be released from the microparticles as the polymeric excipient bioerodes. By an appropriate selection of polymeric materials a microparticle formulation can be made such that the resulting microparticles exhibit both diffusional release and biodegradation release properties."); col. 10:51-11:5; col. 12:1-4.

Lapka '244: Abstract; col. 2:35-63; col. 4:35-57 ("Among the bioabsorbable polymer materials suitable for use in the invention may be mentioned poly(lactic acid) or polylactic acid polymers, such as dl-poly(lactic acid) (or poly(dl-lactic acid)) polymers, poly-(glycolic acid) polymers, poly(hydroxybutyric acid) polymers and lactide/glycolid copolymers."); col. 4:58-5:5 ("The solid injectable drug material which constitutes the core material of the microcapsules may be any such injectable drug material for which it is desired to establish a long-acting, sustained release delivery system."); col. 32:5-16; col. 32:20-21; col. 32:28-34; col. 32:35-39 ("The process according to claim 8 wherein the core material is selected from the group consisting of cyclazocine, tetracycline, ehtisterone, digitoxin, antimony potassium tartrate, salmon calcitonin, ACTH, lypressin, sommatostatin, and insulin.").

Kent '189: Abstract; col. 1:12-28 ("The invention relates to a microcapsule composition comprising a core containing at least one water-soluble, hormonally active polypeptide and optionally a polymer hydrolysis modifying agent encapsulated in a biodegradable, biocompatible copolymer excipient. These compositions have sustained release characteristics. More specifically it relates to microcapsules wherein the core contains water-soluble polypeptides which are lutenizing hormone-releasing hormones, or mammalian growth hormones or polypeptides having thymosin-like activity and optionally an organic acid or its salts, or an acidic, neutral or basic inorganic salt which is capable of modifying the hydrolysis rate of the polymer excipient, encapsulated by a biocompatible, biodegradable excipient."); col. 1:50-58; col. 2:4-7 ("The encapsulating material may be a synthetic polymer comprising either poly(o-hydroxycarboxylic acids), poly(lactones), poly(acetals), poly(orthoesters) or poly(orthocarbonates)."); col. 11:5-38; col. 11:39-13:35 ("The number and type of encapsulating excipients which may be effectively used to practice this invention is limited only by the requirements that the material be biocompatible and biodegradable. . . . Various combinations of alpha hydroxycarboxylic acids and certain lactones can be condensed to form such polymers, particularly lactic acid and glycolic acid or combinations thereof. . . . Similar biocompatible polymers based on glycolic acid and glycerol and the like are also known. . . . Several new biocompatible, biodegradable polymers derived from polyorthoesters and polyorthocarbonates also may be effectively used as encapsulating excipients in the practice of this invention. . . . There are also known polyacetals and polyorthoesters useful for this purpose . . ."); col. 17:42-18:67.

Tice '268: Abstract ("A compatible, biodegradable microcapsule delivery system for active ingredients, including hormonally active peptides, proteins, or other bioactive molecules . . ."); col. 1:32-46 ("More recently a polymer of poly(D,L-lactide-coglycolide) (DL-PLG), which is biodegradable and biocompatible with living tissue, has been used in microcapsules for longer acting delivery systems. Systems of microencapsulated active ingredients in polymers and copolymers have been used to achieve controlled release of chemical and biological pharmaceuticals."); col. 1:47-2:14 ("The microcapsule systems described in the above-publications all share a common feature in that the release of the compound is controlled by the porosity and/or erosion of a polymer continuum."); col. 2:45-53; col. 3:40-47 ("It should be noted, however, that other polymers besides poly(D,L-lactide-co-glycolide) may be used. Examples of such polymers include, but are not limited to: polyacetal polymers, polyorthoesters, polyesteramides, polycaprolactone and copolymers thereof, polycarbonates, polyhydroxybuterate and copolymers thereof, polymaleamides, copolyaxalates and polysaccharides."); col. 11:15-41.

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); col. 3:13-18; col. 3:34-38 ("In a preferred technique, one or more finishing coats of a second solution containing the same or another biocompatible polymer without the carrier is applied to provide an impermeable or substantially less permeable outer surface."); col. 4:29-34 ("In this embodiment, active factor 26 is incorporated within the membrane wall 12. The outer membrane surface 28 is nonporous, while porous inner membrane surface 22 allows for the diffusion therethrough of active factor 26."); col. 4:66-5:11 ("The membrane of the channel may be fabricated from any biocompatible polymers, such as, for example, polyethylene

vinyl-acetate (EVA). . . . Preferable acrylates include methacrylates or hydroethylmethacrylates. The membrane instead may be composed of a bioresorbable biocompatible polymer, such as a polyanhydride, polyester, or mixtures thereof."); col. 5:18-28 ("In a preferred embodiment of the invention, the outer surface of the membrane is impermeable to solutes of any size, while the inner membrane surface contains pores [that] enable the active factors to diffuse out of the membrane and into the lumen of the channel."); col. 5:44-6:10; col. 6:17-22 ("The layering procedure allows deposition of an impermeable coat on the outer surface of the device, insuring that the active factors incorporated into the membrane walls will be inhibited from diffusing through the external surface, and will diffuse only through the inner membrane surface into the lumen of the channel."); col. 9:18-10:3; col. 10:10-12.

Folkman '560: Col. 1:56-2:23; col. 2:43-68; col. 3:18-23 ("The polymer matrixes, which are suitably used in the present invention, are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:36-51 ("Typical polymeric material suitable for forming the matrix . . . include . . . alkylene-vinyl acetate copolymers . . . crosslinked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:52-4:26 ("In the presently preferred embodiment the polymeric materials useful for forming the matrix are the ethylene vinyl ester copolymers of the general formula . . ."); col. 8:17-18; col. 11:56-12:20; col. 12:28-31; col. 12:36-43; col. 12:52-54 ("The therapeutic system for the administration of insulin according to claim 1, wherein the polymeric matrix is ethylene-vinyl acetate copolymer."); col. 12:59-61.

Cohen '496: Abstract; col. 2:46-66 ("In general, the invention features an improved method of making such a body, in which a biologically active material and the polymer below the glass transition temperature of the polymer and compressing the mixture above the glass transition point of the polymer. In preferred embodiments, the polymer is an ethylene-vinyl ester copolymer of the general formula . . ."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:65-4:39 ("In a presently preferred embodiment, the polymeric materials useful for forming the matrix are the ethylenevinyl ester copolymers of the general formula . . ."); col. 9:40-10:17; col. 10:18-32.

Schiraldi '243: Col. 1:58-60 ("Other polymers that might be added are vinyl copolymers, polysaccharides, gelatin and collagen."); col. 2:30-51; col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 3:14-34; col. 4:67-

5:27; col. 10:3-7; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Helwing '868: Abstract ("The compositions may either be in capped form or leashed to a polymeric backbone. . . . The primary uses of the compositions are in controlled release applications such as drugs . . . or in any application where predictable hydrolytic release of the active agent is desirable."); col. 1:6-16 ("The present invention relates generally to compositions of matter and more particularly to covalently bonded compounds composed of active agents containing reactive functional groups The primary uses of the invention are in hydrolysable controlled release utilizations of active agents in such areas as pharmaceuticals, insecticides, herbicides, and the like."); col. 1:19-37 ("In addition . . . it may be highly desirable to have a system that permits the continuous controlled release of an agent . . ."); col. 1:38-2:11 ("One of the most common methods of achieving predictable controlled release mechanism of an active chemical agent is to encapsulate the agent with another material which gradually degrades in the desired medium. . . . A similar method is to trap molecules of the active agent within a surrounding polymer matrix. The matrix structure is such that exposure to an environmental material, usually water, causes the matrix structure to gradually degrade until the surrounding matrix structure is decomposed to the extent that the active agent molecule is permitted to escape into the environment. . . . The Heller, et al. patent utilizes a polymer structure . . . subject to hydrolysis, that is, it is subject to degradation in a gradual manner upon contact with water."); col. 2:12-24 ("The usefulness of structures such as that taught in Heller, et al. patent is significantly dependent upon the unique bioerodable, or hydrolysable, bonding structure . . ."); col. 2:25-37 ("The bonds so formed between the ketene acetals or vinyl ethers and hydroxyl groups are readily hydrolysable under even mildly acidic conditions. It is postulated that similar results will be obtained between various other functional groups on active agents and ketene acetals or vinyl ethers, and that these linkages will be hydrolysable with degradation of the covalent bond in the presence of water providing an ideal mechanism for controlled release of chemical or biological agents."); col. 38-53 ("In the present invention, as active agents will be bonded directly to the controlled release matrix, specific structural design of the base component system will most directly affect control over the hydrophobicity of the overall matrix."); col. 2:55-3:27; col. 3:37-43 ("It is an object of the present invention to provide an aggregation of useful chemical compounds wherein a chemically active agent via its polar active (PA) functional groups is covalently bonded with a carbonium ion mechanism ("CIM") base group, the bond therebetween being hydrolysable in a predictable manner, resulting in controlled release."); col. 3:47-50; col. 3:62-66; col.3:67-4:17 ("The present invention is an aggregation of compositions consisting of a hydrolysable covalent bond formed between a base structure and an active agent structure. . . . The combinations are particularly adapted for use in controlled release of the active agents by way of hydrolysis. The usefulness of the combinations of the present invention is found in a wide degree of chemical and biological applications including drugs . . ."); col. 4:18-38 ("The inventive compositions of matter have the common property that the covalent bond joining the active agent to the base component is predictably hydrolyzable."); col. 4:39-5:6; col. 5:7-46; col. 5:47-50 ("An advantage of the present invention is that new compositions of matter may be created which are subject to predictable hydrolysis under selected environmental conditions."); col. 5:59-62; col. 6:1-4; col. 6:9-18; col. 6:31-34; col. 6:20-64; col. 7:3-20 ("Each of the compositions of the present invention has two distinct moieties joined by a

hydrolyzable covalent bond. . . . The active component will have this chemical or biological effect when it is in its free molecular form but will not have the same effect when it is restricted in the inventive composition by the covalent bond. The hydrolytic decomposition of the covalent bond will act to release the agent so that it may again act in its original molecular form."); col. 7:21-8:50 ("Polymeric support substrates for the leashed systems would include polyvinyl alcohol, dextran, cellulose and similar polyhydroxy polymers."); col. 8:51-9:29 ("The common thread found in the various active agents is that each include one or more functional PA subgroups which are capable of forming the desired hydrolyzable covalent bond with the CIM subgroups of the base component in a predictable manner."); col. 9:30-52 ("With respect to other active agent functional PA groups and CIM base components, the bond structure will not be a pure orthoester linkage but will be of a similar hydrolyzable nature."); col. 9:64-10:9; col. 10:23-11:32; col. 11:33-12:48 ("However, in the presence of water, the orthoester-type linkage is subject to hydrolysis as shown in equation EQ-2 and the Z group representing either the ketene acetal or thioacetal."); col. 12:49-13:5 ("The hydrophobicity of the inventive compositions may be altered such that the composition hydrolyzes at different rates."); col. 19:57 ("As is clear from the above, the scope of possible compositions that can be created according to the present invention is extremely broad. . . . All of the inventive compositions are such that they may be created by the process of the present invention and all will be similar in that the CIM and PA groups will form a hydrolyzable covalent bond which will act to keep the inventive composition intact under environmental conditions until hydrolysis occurs."); col. 20:18-37 ("Timed-release drugs for controlled introduction into the blood stream or other body tissues or cavities are well known, including compositions referred to as pro-drugs. The inventive compositions are extremely well adapted for use in this field. . . . Along these lines, the inventive systems could be used to deliver not only general drugs, but cancer drugs, hormones, vitamins, fungicides and even used as a more durable sunscreen."); col. 20:46-54; col. 20:55-68 ("The preferred embodiment of the present invention may also be applied to a surface as a film of uniform consistency for use in several areas of application. . . . The chemically linked nature of the controlled release matrix affords not only the ability to apply such films, but permits the most compact physical structuring possible in a controlled release matrix as well as an assured even distribution of the desired agent."); col. 21:27-41; col. 21:42-46 ("The composition of claim 1 wherein said covalent bond is predictably degradable via hydrolysis such that the active agent component may be released in a controlled release manner under selected environmental conditions."); col. 21:47-53; col. 21:61-68; col. 22:1-61; col. 22:62-66; col. 22:67-23:3 ("The composition of claim 1 wherein the covalent bond is destructible via hydrolysis at a predictable reaction rate in a specified environment to yield a hydrolytically degraded base component and the active component as separate molecules."); col. 23:4-col. 24:27.

Valentini '029: Col. 3:15-25 ("The semipermeable nerve guidance channels of the present invention can also be biodegradable.").

Greco '135: Abstract; col. 1:19-26 ("This invention relates to methodology for the surface modification of surgical implants permitting the binding of drugs which, after implantation, are slowly released. More particularly, this invention relates to improved surgical implants having sustained, localized delivery of pharmacological agents such as extended antibiotic activity or reduced thrombogenicity, and methods for producing same."); col. 1:29-2:59 ("The surface modification of surgical implants by the adhesion of pharmacological agents

for the purpose of minimizing infection and prosthesis rejection is well-known and has generated broad interest for some time. . . . The present Application is therefore an effort to further disclose and particularize this aspect of the invention, i.e., the development of the antibiotic bonded prosthesis utilizing an anionic surfactant and the oppositely charged drug, antibiotic or other agent or factor."); col. 3:8-19 ("An object of the present invention is to provide improved surfactant-modified implantable devices having a drug, including antibiotics, antithrombogenic agents, thrombolytic agents, disinfectants, etc., bound to the surface thereof. . . . Another object of the present invention is to provide an improved implantable device having a drug bound thereto of improved release times."); col. 3:22-27; col. 3:30-43; col. 4:2-39; col. 5:30-6:58 (disclosing process by which antibodies can be bound to thermoplastic substrates); col. 7:46-9:3; col. 9:10-12.

Bawa '279: Abstract; col. 1:16-36; col. 2:27-35 ("With the foregoing and other objects in view, the invention herein provides a sustained-release polymeric hydrogel dosage form useful for topical, systemic or transdermal administration of a medicinal agent comprising one or more polymerizable hydrophilic polymers, an ion-exchange resin, a cross-linking agent and optionally one or more hydrophobic polymers."); col. 2:39-46; col. 2:47-68 ("The preferred hydrophilic monomers are the hydroxyalkyl esters, specifically hydroxyethyl methacrylate (HEMA)."); col. 4:14-25; col. 6:40-44 ("The invention contemplates a variety of processes for preparing the sustained-release polymeric hydrogel dosage form whereby the medicinal agent is retained by the polymeric matrix and, upon tissue contact, is gradually released into the tissue."); col. 7:15-21; col. 8:1-6; col. 8:29-49; col. 8:54-55; col. 8:66-68; col. 11:42-54; col. 13:10-17; col. 13:26-14:14.

Aebischer '627: Col. 3:23-49 ("In addition, these polymeric materials have the capacity for sustained release of the embedded substance at a controlled rate."); col. 3:57-4:3 ("The polymeric insert includes pores having a molecular weight exclusion of from about 1 kD to about 1,000 kD, but preferably from about 25kD to about 100 kD. In one preferred embodiment, the polymeric insert includes a hydrophobic matrix such as ethylene-vinyl acetate copolymer."); col. 6:52-59 ("the insert may be composed of any biocompatible material having the desired pore size and being composed of materials which do not limit the activity of the substance embedded therein. . . . [H]ydrophobic matrices such as ethylene vinyl acetate are particularly useful."); col. 7:3-12 ("One way of providing the source of neurotransmitter include incorporating it into the polymeric insert. The encapsulating material provides a protective environment for substances such as neurotransmitters or cell growth factors embedded therein, while affording sustained release of the substance at a controlled rate therefrom."); col. 7:13-28; col. 7:29-56 ("The release rate may also be controlled by the amount of pure, impermeably polymeric material coating the effector substance-embedded insert; the more (or thicker the) coatings, the slower the release rate. Materials such as polyurethane or pure ethylene-vinyl acetate are particularly useful for this purpose."); col. 10:31-34 ("To retard dopamine release, three coats of 10% EVAc were applied to each rod by repeated immersion . . ."); col. 14:29-32; col. 14:45-49; col. 14:57-58.

Wood '066: Abstract ("A controlled-release bandage containing therapeutic agents in a poly(vinyl alcohol) cryogel is disclosed. The bandage may include . . . hydrophobic particles to further insure controlled and constant release of therapeutic agents."); col. 2:56-66 ("Bandages comprising cryogel and therapeutic agents are used to provide a protective covering and to

provide a controlled and uniform administration of therapeutic agents to sites of trauma such as wound, thermal or chemical burns, ulcers, lesions or surgical sites. Cryogel bandages may include . . . particles having hydrophobic properties, which absorb the therapeutic agent and release it in an uniform and controlled manner."); col. 3:47-4:36; col. 7:6-32 ("The release of therapeutic agents from the bandage has been found to be further controllable by including insoluble particles capable of adsorbing or forming salts with the therapeutic agent in the bandage. . . . Other examples of suitable insoluble particles include hydrophobic resins, silica, hydroxyl apatite and aluminum oxide."); col. 7:43-50; col. 8:55-56; col. 26:8-18 ("The bandage of claim 1 wherein the insoluble particles capable of adsorbing or forming salts with the therapeutic agent are a hydrophobic resin particles.").

Strecker '746: Abstract; col. 1:63-2:2; col. 2:21-32; col. 3:5-17 ("Another sensible advanced version is characterized in that medications in the lining are dissolved in the wrapping material or included in the form of beads."), ("It can be practical for there to be more or less openings in the wall of the lining next to the lumen than there are in the wall next to the inner surface of the vessel. The ratio can be exploited to prescribe the dosage of medication to the lumen or wall of the blood vessel."); col. 3:17-26 ("The wrapping material can also to advantage be biodegradable When the material is biodegradable, the medication will be released not by diffusing out of the vehicle but by escaping as the vehicle that the medication is dissolved in or that accommodates the beads that encapsulate the medication at its surface decomposes and by accordingly coming into contact with body fluids."); col. 3:27-33; col. 5:10-12; col. 5:38-41; col. 6:1-17; col. 6:35-38; col. 7:16-37 ("a lining impregnated with medication for delivery to a wall of said body lumen"); col. 7:48-65; col. 8:19-10:19; Figs. 7 & 8.

Lambert '246: Abstract ("The biologically active compound is, therefore, released only at the site where it is desired, i.e., where the prosthetic article is positioned."); col. 1:46-55 ("Release of heparin from intravascular catheters in quantities sufficient to decrease thrombosis on the catheter has been achieved by either covalently bonding a charged molecule to a polymer or incorporating a large nonmobile charged molecule on the surface of the polymer . . ."); col. 1:57-61; col. 2:15-34 ("Increasing the lipid solubility of the compound slows release from the polyurethane, and increases the tissue retention. More lipid soluble compounds are, therefore, preferred agents for use in the practice of the present invention."); col. 2:38-40 ("In accordance with the present invention, there is provided a method for preparing a system suitable for localized delivery of biologically active compounds to a subject."); col. 2:40-49; col. 2:53-65; col. 7:31-33 ("The results of this example demonstrate that polyurethane stent coatings can concentrate and release lipophilic drugs in vitro."); col. 8:58-9:4 ("Adventitia overlying the stent contained 360 times the concentration of forskolin in the blood and 305 times the concentration of forskolin in the contralateral artery. . . . In a similar model, etretinate, a retinoic acid analog, develops concentrations in the media of 250 ng/mg tissue at 24 hours. At 24 hours, this concentration was over 2000 times the concentration in the blood."); col. 9:31-37 ("These data demonstrate that a polyurethane coated nitinol stent is capable of delivering a lipophilic drug in high local concentration in the vessel wall. The large 450 fold differential of local tissue levels of forskolin over blood levels reflects the capability of this delivery system to provide high local concentration and potentially higher efficacy, with lower risk of systemic side effects."); col. 10:47-50; col. 10:62-64 ("The drug delivery system of claim 1 wherein the biological agent is absorbed substantially throughout the entire thickness of the polyurethane elastomer coating.");

col. 11:16-17 ("The drug delivery system of claim 8, wherein said biologically active compound is a lipophilic compound."); col. 11:30-31; col. 11:36-40; col. 12:12-13; col. 12:17-21; col. 12:53-54.

Bellamkonda '029: Col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 5:32-48 ("The agarose hydrogels of this invention may be used as a carrier to present various ECM proteins or peptides We prefer covalent immobilization of ECM proteins to the hydrogel backbone."); col. 7:26-32 ("In a preferred embodiment, laminin-derived oligopeptidic fragments . . . are coupled to the hydroxyl backbone of agarose, using any suitable method."); col. 9:36-48 ("These growth factors may be incorporated into the channel membrane . . ."); col. 11:7-8 ("Additionally, the membrane may be composed of a biodegradable material."); col. 11:41-50; col. 12:13-16 ("Preferably the permselective membrane is fabricated to be impermeable to some of these substances so that they are retained in the proximity of the regenerating nerve ends."); col. 12:42-49; col. 12:50-56; col. 15:67-16:17; col. 23:54-24:55.

Dayton '382: Abstract ("The stent is then coated with a polymer . . . which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids, with the equilibrium being controlled by charge distribution, concentration and molecular weight of the bioactive substance in relation to the pore size of the polymeric carrier for controlled prolonged release of said bioactive substance."); col. 1:9-17 ("The present invention relates to an improved percutaneously inserted endoprosthesis device which is permanently or temporarily implanted within a body vessel, typically a blood vessel. More particularly, the present invention relates to a new procedure for administering localized bioactive substances via prosthesis designs . . ."); col. 3:36-39; col. 3:62-4:17 ("Among these polymers are polymers having a microporous structure, such as . . . biodegradable polylactic acid polymers, polyglycolic acid polymers . . ."); col. 4:24-33 ("A bioactive substance is preferably admixed in the polymer for elution from the microporous structure of the stent or coating on the stent after implantation. The rate of elution of the bioactive substance is controlled by selecting a pore size for microporous structure . . ."); col. 6:64-7:7 ("Also included in the polymer is a bioactive substance having a charge distribution, concentration and molecular weight selected which achieves an equilibrium in relation to the pore size of the polymeric carrier with said surrounding body tissues or fluids."); col. 7:8-14; col. 7:20-23.

Burt '036: p.4:19-33 ("Within one aspect of the present invention, compositions are provided . . . comprising (a) an anti-angiogenic factor and (b) a polymeric carrier. A wide variety of molecules may be utilized within the scope of the present invention as anti-angiogenic factors Similarly a wide variety of polymeric carriers may be utilized, representative examples of which include poly(ethylene-vinyl acetate) . . . and copolymers of polylactic acid and polycaprolactone."); p.10:17-25; p.14:9-27; p.21:2-4; p.51:1-52:35.

Goldin '568: Abstract; col. 1:21-34 ("In certain circumstances, another desirable use of controlled release methods is to target the delivery of a therapeutic agent specifically to the tissue or site that can benefit from the presence of such an agent."); col. 1:35-41 ("Several classes of controlled release strategies have been developed, principally involving: (a) release by controlled diffusion; . . . and (c) release limited by chemical control of the interaction of the agent with a substrate to which it is adsorbed or bound."); col. 1:43-62 ("Release by controlled diffusion may be accomplished by means of containment of the therapeutic agent within a substrate whose small pore size and/or tortuosity of diffusion path thereof limits the diffusion of said agent through the substrate. . . . The therapeutic agent can be incorporated within the diffusion-limiting substrate Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:8-16 ("Towards that end, diffusion-controlled slow release devices have been fabricated from biodegradable polymers . . ."); col. 2:24-28; col. 3:42-53 ("Release by chemical control most commonly involves chemical cleavage from a substrate to which a therapeutic agent is immobilized, and/or by biodegradation of the polymer to which the agent is immobilized."); col. 3:54-65 ("Another variant of release by chemical control termed herein "controlled noncovalent dissociation or 'CND'", relates to release resulting from dissociation of an agent that is bound temporarily by non-covalent binding of the agent to a substrate."); col. 4:25-45 ("The microskin is specifically tailored to bind macromolecules . . . noncovalently by cooperative secondary bonds, and slowly release the macromolecules by controlled non-covalent dissociation (CND)"); col. 4:63-66; col. 6:1-19 ("Because preferred embodiments of the CND controlled Release Device and methods of use thereof employ membranes whose pore size is normally much greater than molecular dimensions, the kinetics of release are governed primarily by the strength and number of the reversible cooperative secondary bonds which immobilize said protein for CND."); col. 6:20-29 ("Limitation of the toxicity associated with the macromolecules to be released results from selective delivery to the site of action in the amounts and at the time needed. While in practice, the temporal and spatial selectivity of the current invention may not be absolute, it is clearly an improvement over more conventional modes of delivery . . ."); Fig. 1A; Fig. 1B; col. 8:65-9:6; col. 9:18-22; col. 9:23-30; col. 9:43-50 (" . . . delivery from controlled release devices can be controlled by diffusion out of said device, dissociation of chemical bonds, and the like."); col. 9:51-55; col. 10:45-54; col. 17:40-54 ("[S]ynthetic polymers . . . may be derivatized to attach functional groups which may react under appropriate circumstances to form covalent bonds with the macromolecules one wishes to bind and release in a controlled manner."); col. 20:9-12 ("By appropriate use of said Device, one can selectively target a therapeutic site . . ."); col. 20:46-21:19 ("[W]hen the pore size of the underlayment and/or the microskin approaches submicron dimensions and/or the thickness of said Devices approaches millimeter dimensions or greater, diffusion of the agent to be delivered out of said device may contribute to or even be the predominant process governing controlled release from said Device."); col. 21:47-49 ("A coating of a permeable guide tube, with a secondary membrane designed to exclude macromolecules from without."); col. 27:10-18; col. 32:26-31.

Palmaz '762: Col. 10: 28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '337: Col. 9: 24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Zaffaroni '254: col. 2:6-9 ("Still another approach has been to enclose the drug within a single capsule having a polymeric wall or walls through which the drug can pass, for example, by diffusion."); col. 2:16-26 ("Additionally, these prior art devices have generally been based on the use of a single material, such as silicone rubber polymers, especially polydimethylsiloxane, as the diffusion control membrane. In large part, these polymers were selected because of their permeability to some important drug molecules. But, it has been found that mere high permeability without consideration of release rate controlling properties can be a significant disadvantage which defeats the primary object of an acceptable drug delivery device."); col. 4:54-58 ("In operation, solid drug carrier 13 serves as a reservoir 12 by supplying dissolved drug 14 to the micropores 15 of wall 11 as drug molecules move through the carrier to bathe the inner surface of wall 11."); col. 7:18-25.

Langer I: p.29 ("In the bioerodible system, the drug is distributed relatively uniformly throughout the plastic as in matrix systems, but it differs from the matrix in that its plastic portion decreases with time. As the plastic surrounding the drug is eroded, the drug escapes. . . . The most popular bioerodible polymers have been absorbable suture materials such as polylactic acid."); p.29-30 ("The second type of chemically controlled system is known as a pendant chain system. In simplest form, the drug is attached via chemical bonds to a polymer backbone. It could also be attached via a spacer group Release occurs when water reacts to break those bonds, thereby freeing the drug. Release rates are adjusted by varying the hydrophilicity of the polymer backbone. Systems could also be designed so that an enzymatic reaction could break the drug-polymer bonds."); p.29 Figure legend ("Chemically controlled pendant chain drug-delivery system. Here, the drug is bound to a polymer backbone and released by hyd[r]olytic or enzymatic cleavage, the key to controlling the medication's delivery.").

Langer II: p.217-18 ("In chemically controlled systems, release is accomplished either by biodegradation of the polymer . . . or by chemical cleavage of the drug from a polymer backbone to which the drug had been bound as a pendent group."); p.218 Fig. 3; p.219 Fig. 4 ("Chemically controlled pendent-chain drug-delivery system. Here, the drug is bound to a polymer backbone and released by hydrolytic or enzymatic cleavage."); p.221-225 ("Contraception" "Immunization" "Anticoagulation" "Cancer" "Insulin Delivery" "Controlled-release formulations may be applied to other clinical areas, including the release of narcotic antagonists, antibiotics, interferons, anesthetics, anti-arrhythmics, and antimalarial drugs.").

Langer III: p.25 ("Matrix Systems"); p.26-27 ("From a chemical standpoint, Heller has considered bioerodible systems in terms of three dissolution mechanisms: [1] water-soluble polymers insolubilized by degradable cross-links; [2] water-insoluble polymers solubilized by hydrolysis, ionization, or protonation of pendant side-groups; and [3] water-soluble molecules. These mechanisms represent extreme cases, and erosion by a combination of mechanisms is possible."); Fig. 3-3; Fig. 3-4; p.27-28 ("In pendant chain systems, a drug is chemically bound to a polymer backbone-chain and is released by hydrolytic or enzymatic cleavage. . . . The polymer

system can be either soluble or insoluble . . . insoluble forms are more desirable for long-term controlled-release implants. The backbone may also be biodegradable or nonbiodegradable. . . . The drug itself can be attached directly to the polymer or attached via a spacer group. The spacer group may be used to affect the rate of release and hydrophilicity of the system.").

Langer & Peppas: Fig. 5; p.80-83 ("Matrix Systems"); p.83 ("Polymers for Diffusion-Controlled Systems"); p.84; p.85 ("Ethylene-vinyl acetate (EVAc) copolymers have found major applications in controlled release of bioactive agents because of their relatively good chemical stability, biocompatibility, and inertness."); Fig. 7; p.86-87 ("Chemically controlled drug release generally involves one of two types of systems: 1) Erodible systems in which the drug is dispersed in a biodegradable polymer and drug release is influenced by the rate of degradation of the polymeric material, and 2) pendant chain systems in which the drug is attached to a polymer through a hydrolytically or enzymatically labile linkage. Drug release is influenced by the rate of degradation of this linkage."); Fig. 8; p.87-100 (describing and identifying polymers for biodegradable drug release systems); p.100-101 ("In [pendant chain systems] a drug is chemically bound to a polymer backbone and is released by hydrolytic or enzymatic cleavage. . . . [I]nsoluble [backbones] are more desirable for long-term controlled-release implants. . . . The drug itself can be attached directly to the polymer or it can be attached via a spacer group. The spacer group may be used to affect the rate of release and hydrophilicity of the system. To achieve near constant release, the cleavage of the drug from the polymer must be the rate-limiting step. . . . There has recently been interest in developing controlled-release systems using pendant chain polymers for clinical applications."); p.114-16 ("Medical applications of controlled-release systems can be divided into four general areas: oral systems, transdermal systems, external implants, and subcutaneous implants.").

Langer IV: p.36 ("In matrix systems, the drug is uniformly distributed through a polymer."); Fig. 2; p.37 ("Two systems of chemical control exist. The first mechanism is bioerosion or biodegradation of the polymer. As the polymer surrounding the drug is eroded, the drug escapes. . . . The second type of chemically controlled system is known as a pendant chain system. In simplest form, the drug is attached via chemical bonds to a polymer backbone. It could also be attached via a spacer group. Release rates are adjusted by varying the hydrophilicity of the polymer backbone. Systems could also be designed so that an enzymatic reaction could break the drug-polymer bonds."); p.37 Fig. 3 ("Idealized diagram of the cross-section of a cylindrical or spherical bioerodible matrix."); p.37 Fig. 4 ("Idealized diagram of a chemically controlled pendant chain drug delivery system. The drug could be connected to the polymer backbone as shown or could be coupled to a spacer group attached to the polymer backbone."); p.41-42 ("The second type of [contraceptive] system is a subdermal implant composed of a biodegradable polymer."); p.44 ("Small (0.3 mm³) injectable pellets of ethylene-vinyl acetate copolymer containing 100 ug of a test antigen, bovine serum albumin, were positioned subcutaneously in mice.").

Langer V: p.24 (" Examples of polymers with these properties include nondegradable polymers such as ethylene-vinyl acetate copolymers (EVAc), and biodegradable polymers such as polylactic or polyglycolic acid.") ("Theoretically, the [biodegradable] polymers should have a hydrophobic backbone, but with water-labile linkage.").

Langer VI: p.115 (One approach that has received increasing attention as a means of prolonging drug release has been the incorporation of drugs in solid polymers (e.g., silicone rubber, ethylene-vinylacetate copolymer). This method permits drugs to be released for long time periods in a controlled fashion."); p.120-124 ("The ideal [biodegradable] polymer would have a hydrophobic backbone, but with water labile linkage.").

Laurencin & Langer: Fig. 2; p.304-306 ("Matrix Systems"); p.306-307 ("Three dissolution mechanisms for bioerodible polymeric devices are found in general: Type 1: water soluble polymers that are made insoluble through crosslinks that are degradable. On exposure to an aqueous environment, crosslinks are broken, polymer dissolves, and release occurs. Type 2: water insoluble polymers that on exposure to an aqueous environment are solubilized by hydrolysis, ionization, or protonation of pendant side groups. Type 3: water insoluble polymers containing hydrolytically unstable backbone linkages. On exposure to an aqueous environment, polymer chains are cleaved to small water soluble monomers."); p.307 Fig. 4; p.308-309 ("In [pendant chain systems], drug is chemically bound to the backbone of a polymer. Release takes place by hydrolytic or enzymatic cleavage. . . . Polymer systems can be soluble or insoluble, and the backbone itself may be bioerodible or nonbioerodible. Soluble backbone chains are generally used for transport functions such as cell targeting; insoluble forms are more desirable for long-term controlled release implants. Drug can be chemically attached to the polymer directly or through a spacer group. The spacer group may be used to affect the rate of release or hydrophilicity of the system."); p.308 Fig. 5 ("Chemically controlled pendant chain drug delivery device. Drug bound to polymer backbone is released by hydrolytic or enzymatic cleavage."); p.313-316 (clinical applications of EVAc and biodegradable polymers).

Langer VII: p.1529 ("Chemical control is accomplished either by polymer degradation or chemical cleavage of the drug from a polymer."); p.1529 Fig.1(B), (C) and (D); p.1530 ("Examples of polymers that perform in this way are non-degradable ethylene-vinyl acetate copolymer and degradable lactic acid-glycolic acid copolymers."); p.1531-32 ("Theoretically, the [ideal surface-eroding] polymer should be hydrophobic but should have water-labile linkages.").

Langer & Moses: p.341-42 ("[W]e proposed that an ideal polymer would have a hydrophobic backbone, but with a water labile linkage."); p.342-44 ("One such report . . . employed the porous ethylene-vinyl acetate copolymer (EVAc) system to provide sustained release of fibroblast growth factor (FGF) or epidermal growth factor (EGF).").

Chien: p.32-33 ("[The hydrolysis-activated] controlled drug delivery system depends on the hydrolysis process to activate the release of drug molecules. . . . The release of a drug from the polymer matrix is activated by the hydrolysis-induced degradation of polymer chains and controlled by the rate of polymer degradation.") ("[The enzyme-activated] controlled drug delivery system depends on the enzymatic process to activate the release of drug. . . . The release of drugs is activated by the enzymatic hydrolysis of the biopolymers by a specific enzyme in the target tissue."); p.37 ("An ideal site-targeting drug delivery system has been proposed . . . constructed from a nonimmunogenic and biodegradable polymer backbone having . . . a drug moiety that is covalently [sic] bonded to the polymer backbone through a spacer and contains a cleavable [sic] group that can be cleaved only by a specific enzyme(s) at the target tissue.").

Thomson: p.34-36 ("The degradation of synthetic polymers is, in general, brought about by simple hydrolysis, although in some cases enzymatic processes assist in the degradation mechanism.").

Hanes & Langer: p. 647 ("Polymers can also be used to deliver vaccines in a controlled manner."); p.648 ("Biodegradable polymeric devices or pendant chain systems are examples of chemically controlled devices. In the former, molecules are typically dissolved or entrapped in a biodegradable, bioresorbable polymer matrix As the polymer degrades and erodes, molecules are released to the surroundings. In pendant chain systems, molecules are chemically attached to the backbone of a polymeric carrier using hydrolytically or enzymatically degradable bonds. In this case, the molecules are liberated as the bonds holding them to the polymer are cleaved."); p.649 Fig. 29.2; p. 652 ("For the present development of vaccine delivery systems, the use of biodegradable polymers presents significant advantages over the use of nondegradable systems."); p.654-55 ("There are many such polymers that may prove useful for controlled delivery of vaccines; however, no degradable polymer systems has been more widely studied with respect to release kinetics than the lactide/glycolide polyesters."); p.655-56; p.656-58 ("Advantages of Controlled Release for Immunization").

Batz: p.26-27 ("Based on their chemical structure polymeric drugs are divided into the following three groups b) Drugs in which the active substance of known biological activity is bound to a polymeric carrier molecule via a functional group."); p.36-43 ("Polymeric drugs formed by covalent bond of known active components to soluble macromolecular carriers"); p.48 ("Polymeric Forms of Deposit Without Covalent Bond Between Drugs and Polymeric Materials.").

Donaruma: p.10 ("Allan, Chopra, Neogi, and Wilkins, in studies concerned with the design and synthesis of controlled release pesticide polymer combinations, investigated the duration of effectiveness of various herbicidal phenoxyacetic acids chemically bound as pendant substitutes to natural or synthetic water-soluble and water-insoluble polymers."); p.17, 19-20 ("[I]t can be seen that in some cases portions of the polymer repeat unit are structurally constituted so that by hydrolysis the polymer chain or a pendant group may be sundered by hydrolysis. . . . Chemically combining a drug in a polymer may offer a means of sustained release and/or prolonged activity of drugs and/or drug latention. These are not new concepts, and examples are reported in the literature.").

Harris I: p.334 ("As reported in this review, our work has involved the syntheses and evaluation of polymers containing pendant aquatic herbicides."); p.344 ("The herbicide release rates of polymers containing herbicides as pendant substituents are extremely slow in water with pH=C at 30°C. The herbicide release rates, however, can be increased by incorporating hydrophilic groups along the polymers' backbones").

Feld: p.113-15 ("One approach to obtaining these formulations has been the synthesis of polymers that contain pesticides as pendent side chains. . . . Pesticide release occurs by the slow, sequential hydrolysis of the pesticide-polymer chemical bonds. This provides a sustained release of the pesticide over an extended period of time. The actual release depends on the nature of the pesticide polymer bond and the dimensions and structure of the resultant macromolecular

combination."); p.116-17 ("It was postulated that increasing the length of the pendent side chain would enhance the hydrolysis of the herbicide-polymer bond."); 117-19 ("Herbicide reactivation was produced enzymatically using lipase, acetylcholinesterase and trypsin.").

Harris & Post I: p.622 ("One approach to obtaining controlled-release pesticide formulations that contain a high percentage of pesticide has been the synthesis of polymers that contain pesticides as pendent side chains. The pesticide is presumably released by the slow sequential hydrolysis of the pesticide-polymer chemical bonds. . . . It was postulated that increasing the length of the pendent side chain would enhance the hydrolysis of the herbicide-polymer bond.").

Harris & Post II: p.225 ("One approach to obtaining controlled-release pesticide formulations that contain a high percentage of pesticide has been the synthesis of polymers that contain pesticides as pendent side chains. The pesticide is presumably released by the slow sequential hydrolysis of the pesticide-polymer chemical bonds. . . . It was postulated that increasing the length of the pendent side chain would enhance the hydrolysis of the herbicide-polymer bond.").

Drobnik: p.2833 ("Water-soluble copolymers based on poly[*N*-(2-hydroxypropyl)methacrylamide] and bearing in their side chains a chromogenic substrate for chymotrypsin were prepared by direct copolymerization or polymeranalogous reaction."); p.2834 ("The bonding of drugs onto macromolecules is an old idea, because it offers a potential optimization of the pharmacokinetics of drugs. The majority of pharmaceuticals are inactive in the macromolecular form and must, therefore, be released in their original active low-molecular weight form, i.e. their attachment to the polymer must be reversible, or degradable."); p.2844-47 ("The results also indicate the general influence of the spacer: the longer the spacer, the easier the cleavage of the enzyme susceptibility bound For practical purposes, that is, enzyme-specific binding of drugs to polymers, the following conclusions can be drawn from the above results . . .").

Allan I: p.17 ("These materials are chemical or physical combinations of known and established pesticides with macromolecules. . . . As the pesticide-polymer combination lies in the soil, a gradual decomposition occurs, and the pesticide is slowly released over the desired and predictable period of time."); p.18-19 ("This situation is avoided by the use of a chemical combination of the butyric acid [herbicide] with the polymeric components of bark. The ester linkage joining the herbicide to the bark will not be easily attacked by any β -oxidase and the butyric acid herbicide is thereby stabilized. Essentially, the only butyric acid herbicide available for β -oxidation is that continuously being released from the bark. This release will occur whether the combination lies in or on the surface of the soil since attack by moisture, micro-organisms and the weather can occur in either of these zones.").

Allan II: p.349 ("We have therefore investigated the potential of pesticide-polymer combinations as a means of securing controlled release of a biodegradable pesticide in approximately the correct amount needed over an appropriate period of time. . . . Two distinct approaches are not reported. (a) Pesticide release by diffusion through polymers, and (b) pesticide release by degradation of a polymer containing the pesticide as a pendent side chain. . .

. For case (b) the pesticides . . . are chemically attached as a pendent substituent to a natural or synthetic water-soluble or insoluble polymer . . ."); p.350 ("In the biological environment, side chain degradation occurs so that the chemical bonds holding the pesticide within its polymeric prison are sequentially broken to provide a sustained release of the pesticide over an extended period of time. The rate of release will clearly be determined by the nature of the pesticide-polymer bonds, the chemical characteristics of the pesticide and polymer and the dimensions and structure of the resultant macromolecular combination.") ("Although developed for developed for forest pest control the systems described should be broadly applicable to the controlled release of other biologically active substances.").

Allan III: p.173: ("Controlled release from polymeric matrix"); p.173-74 ("Representative of the other end of the thermodynamic spectrum is the situation where the pesticide is firmly attached to the substrate by a high energy covalent bond. Release of the pesticide then involves the cleavage of a definite identifiable chemical bond such as an ester or amide. . . . The simplest [arrangement] has the pesticide attached as a pendent substituent to a natural or synthetic water-soluble or insoluble polymer having a replaceable hydrogen The chemical bonds holding the pesticide within its polymeric prison are sequentially broken to provide a sustained liberation of the pesticide over an extended period of time."); p. 176 ("Moreover, the [controlled release] concept is broadly applicable to the release of other biologically active substances.").

Jakubke: p. 281 ("Observations in our laboratory indicated that an enzymatic cleavage of carrier-bound biologically active substance of low molecular weight is fundamentally possible. As part of a general model study of enzymatic reactions with insoluble substrates we investigated the α -chymotrypsin-catalyzed hydrolysis of Sepharose-bound L-phenylalanine 4-nitroanilide. As a spacer, 1 or 2 mol of 6-amino-hexanoic acid, respectively, were inserted between the gel matrix and the low-molecular weight substrate."); p. 282 ("The course of hydrolysis was proportional to time during the first 15 min. About 70% of total bound (ϵ Ahx)₂-Phe-NA was hydrolyzed after 4 hr."); Fig. 2 ("Dependence of hydrolysis on the enzyme concentration at 25°C."); p. 283 ("In agreement with this the substrate dependence of the hydrolysis rate shows the same course as observed with Glt-Phe-NA.").

Engelberg & Kohn: p. 292 ("For example, degradable polymers are now being investigated as intra-luminal grafts, stent-like devices that are implanted into coronary arteries in an attempt to prevent the collapse and the reblocking (restenosis) of blood vessels after successful balloon angioplasty."); p.293 ("Since surface-eroding, slab-like devices tend to release drugs embedded within the polymer at a constant rate, poly(ortho esters) appear to be particularly useful for controlled release drug delivery. It is not surprising that there are a significant number of publications describing the use of poly(ortho esters) for drug delivery applications."); p. 293-94 ("PLA, PGA and their copolymers are also being intensively investigated for a large number of drug-delivery applications. . . . PLA, PGA and their copolymers are currently the most widely used synthetic degradable polymers in human medicine."); p.294, Table 1; 294-95 (The potential applications of these [PHB polymers] include biomedical applications such as controlled drug release . . ."); p.295 ("Later, it was discovered that PCL can also be degraded by a hydrolytic mechanism under physiological conditions. Under certain circumstances, cross-linked PCL can be degraded enzymatically, leading to

enzymatic surface erosion."); p.296 ("It is interesting to note that despite its versatility, PCL has so far been predominantly considered for controlled-release drug-delivery applications.") ("[The low hydrolytic stability] was later recognized as a potential advantage by Langer et al. who suggested the use of polyanhydrides as degradable biomaterials."); p. 297; p. 298 ("Poly(ortho esters)"); p. 298-99 ("PGA"); p. 299 ("PLA"); p. 300 ("PBH and copolymers with HV"); p. 301 ("PCL") ("Because of their low mechanical strength and high hydrolytic reactivity, the two polyanhydrides tested appear to be limited to drug-delivery applications."); p. 302.

Roseman & Mansdorf: p. 91-105 ("The objective of this chapter is to describe the development of a bioerodible polymer implant that would release an incorporated drug by zero-order kinetics for at least 6 months. A further objective is the development of a system where drug release and polymer erosion take place concomitantly so that no polymer remains when the drug is depleted."); p. 107 ("There have been, however, studies where polymer-drug complexes have been synthesized, the major objective of which was to provide a controlled or prolonged action of the drug by the natural hydrolysis or biological scission of the covalent polymer-drug bond. In this way, mescaline, insulin, salicylic acid, D-isoproterenol, naloxone, plant cytokinins, 2,4-dichlorophenoxyacetic acid, norethindrone, and cortisol-21-acetate have been attached to and released from various synthetic and natural polymers through covalent bonds such as amide, ester, aso, carbamate, carbonate, oxime ester, and hydrazone."); p. 108 ("GAGs are biodegradable by enzymatic means normal to the host."); 108-109 ("We have taken advantage of various types of functional groups available on the GAG backbone (carboxyl, primary and secondary hydroxyl, and sulfate) in preparing and testing a series of complexes in which the drug was bound directly to the polymer or via an intermediate linking group such as an amino acid or other such bioacceptable entity. . . . Current work with other drugs bound to the GAG backbone by the same and different bond types (i.e., carbamate, ionic) will be reported in the near future."); p.110; p. 111 ("Amide and ester bond types were chosen because both are susceptible to chemical hydrolysis and both are prevalent naturally and thus are potentially dependable by enzymes."); p. 112 Fig. 2 & 3; p. 112-113 ("The release was pseudo-first order with a release rate constant of 0.10 day^{-1} and a half-life of 3.8 days. This is what one would expect if the rate-determining stem for release is the chemical hydrolysis of the ester bond in the prodrug."); p. 113 ("Reactions on polymers, such as the hydrolytic cleavage of GAG-drug bonds, has been shown to be affected by polymer chain length and conformation, steric isolation, and neighboring group effects."); p. 114; p. 115 ("Even though the amid bond between the drug and the polymer may hydrolyze slowly over this period and release cysteine, the rate-determining step for release was probably enzymatic breakdown of the complex. . . . A large advantage of using glycosaminoglycans as drug carriers is that they are biocompatible and biodegradable."); p.116 ("Chloramphenicol-GAG ester complexes released Cpl quickly by scission of the ester bond. Cysteine-GAG amide complexes degraded much more slowly and probably through enzymatic hydrolysis of the polymer or polymer-drug bond."); p. 117 ("Nevertheless, this concept provides an interesting base from which to design a drug release system; the rate of release may in principle be engineered by the judicious choice of drug-GAG bond based on the hydrolytic stability of the bond.").

Lee & Good: p. 2; p. 2-3 ("As a result of research on improved absorbable sutures, poly (lactic acid), poly (glycolic acid), and lactic/glycolic acid copolymers, which hydrolyze to natural metabolites, have been developed for drug delivery purposes."); p. 3 ("[P]olymer erosion

can be controlled by the following three types of mechanisms: (1) water-soluble polymers insolubilized by hydrolytically unstable cross-links; (2) water-insoluble polymers solubilized by hydrolysis, ionization, or protonation of pendant groups; (2) hydrophobic polymers solubilized by backbone cleavage to small water soluble molecules. . . . [O]ther commonly used bioerodible/biodegradable polymers include polyorthoesters, polycaprolactone, polyaminoacids, polyanhydrides, and half esters of methyl vinyl ether-maleic anhydride copolymers.") ("Drug-Polymer conjugates. This system involve drug molecules chemically bounded to a polymer backbone. The drug will be released through hydrolytic or enzymatic cleavage. . . . The attachment of drugs to macromolecular carriers alters their rate of excretion from the body and provides the possibility for controlled release over a prolonged period. . . . Both natural polymers such as polysaccharides and synthetic polymers such as polylysine, polyglutamic acid, polyphosphazenes, copolymers of vinylpyrrolidone, copolymers of 2-hydroxypropylmethacrylamide, and etc. have been used as drug carriers."); p. 4 ("The drug-polymer linkage may be covalent, ionic, or through some weaker secondary molecular forces. The drug may be part of the polymeric backbone or attached to the side-chain either directly or through a spacer group. The spacer groups is generally selected in such a way that it may be hydrolyzed or degraded enzymatically under specific environmental conditions. Examples of such drug-polymer conjugates include the attachment of ampicillin, 6-amino-methacrylamide copolymers, methotrexate to poly (L-lysine), and norethindrone to poly(hydroxyalkyl)-L-glutamine. In addition to diffusion rate limitations as described in the next section, the drug release rate is primarily governed by the rate of cleavage of the drug from the polymer."); p.5- 7 ("Matrix Diffusion"); p. 7 ("Polymer Erosion. The release of a dissolved or dispersed drug from an erodible polymer matrix can be controlled by a variety of mechanisms ranging from hydrolysis/enzymatic cleavage as discussed in the previous section to swelling and dissolution."); p. 17 ("An important example of these processes is the controlled release of bioactive molecules from polymeric membranes. Many pharmaceutically active agents have been released at controlled rates from hydrophobic polymer carriers. . . . In 1976 it was demonstrated that hydrophobic polymers, in particular ethylene-vinyl acetate copolymer (EVAc), could be used to release molecules with molecular weights greater than 1000."); p. 182 ("Enzyme-Degradable Hydrogel"); p.188-200; p. 214-230.

Langer & Folkman I: p. 179 ("Therefore, we turned to other polymers such as ethylene-vinyl acetate copolymer . . ."); p. 180-83; p. 183-84 ("Poly(vinylalcohol), Hydron, and ethylene-vinyl acetate copolymer were examined for their ability to release soybean trypsin inhibitor . . ."); p. 185-88; col. 188-191 ("The following three studies demonstrate that the pellets are releasing macromolecules in biologically active form."); p. 191-92 ("The present experiments show that macromolecules with a wide range of molecular weights can be delivered in significant quantities from polymeric vehicles that are not inflammatory when implanted in animals. These polymers can release macromolecules in biochemically and biologically active form for periods in excess of 100 days as measured by direct assays. . . . The eventual clinical application of these polymers for delivery of macromolecules such as insulin, heparin, or enzymes may merit consideration.").

Langer & Folkman II: p. 798-99 ("Polyvinylalcohol, Hydron and ethylene-vinyl acetate copolymer were examined for the ability to release soybean trypsin inhibitor . . .")

("These studies show that sustained release of proteins and other macromolecules from polymeric vehicles can be achieved over prolonged periods.").

Langer VIII: p. 1 ("One approach that has received increasing attention as a means of prolonging drug release has been the incorporation of drugs in solid polymers (e.g. silicone rubber, ethylene-vinyl acetate copolymer). This method permits drugs to be released for long time periods in a *controlled* fashion."); p. 10 ("Controlled-release polymer formulations may also find applications in other clinical areas. One such area that has received increasing attention is the controlled release of antibiotics. . . . Polymers have also been used to deliver anesthetics, anti-malarial drugs, anticoagulants, and drugs to combat cardiac arrhythmia."); p. 27 ("However, several recent studies have demonstrated that matrix systems can be engineered to permit continuous release of large molecules. By solvent casting normally impermeable polymers such as ethylene-vinyl acetate copolymer in volatile solvents . . . along with powdered macromolecule, a series of interconnecting channels is formed within the polymer matrix. . . . These macromolecular delivery systems now open the possibility of delivering many important large molecular weight compounds such as insulin or interferon for prolonged periods."); Fig. 20; p. 28-29 ("[T]he volume of bioerodible systems becomes smaller with time, and, as the polymer surrounding the drug is eroded, the drug escapes."); p. 30 ("Erosion could be caused by hydrolytic or enzymatic cleavage of the crosslinks so that the ultimate degradation products are high molecular weight polymers. Alternatively, the degradation could occur in the polymer backbone so that the degradation products have low molecular weights."); p. 31-32 ("The third category of biodegradable systems are water-insoluble polymers that undergo hydrolytic or enzymatic backbone cleavage and are solubilized to small water-soluble molecules. . . . The best example of this class of polymer is polylactic acid or copolymers of lactic acid and glycolic acid."); p. 32 ("Sidman and coworkers . . . developed a peptide copolymer of glutamic acid and ethyl-*L*-glutamate."); p. 32-34 ("Pendant Chain Systems: In this type of system, a drug is chemically bound to a polymer backbone and is released by hydrolytic or enzymatic cleavage. The use of these therapeutic agents has received considerable attention in drug-related research. The major thrust so far has been the design of polymer-drug complexes for short-term use that can reduce toxicity, increase therapeutic efficiency, or be targeted towards specific cells or organs. . . . The drug itself can be attached directly to the polymer or it can be attached via a spacer group. The spacer group may be used to affect the rate of release and the hydrophilicity of the system. . . . To achieve near constant release, the cleavage of the drug from the polymer must be the rate-limiting step."); Fig. 22.

Langer & Folkman III: p. 114-15; p.117-18 ("Demonstration of Long-term Release") ("In initial trials with soybean trypsin inhibitor . . . protein was released . . . least rapidly from ethylene-vinylacetate copolymer."); p. 119-20 ("When tested in this fashion, ethylene-vinylacetate copolymer pellets continued to produce zones on these slides for over 100 days, indicating that the pellets were releasing nearly 1 ug/day or biochemically active protein."); p. 123-25 ("Insulin Delivery"); p. 125-26 ("Immunization Procedures").

Rhine: p. 265 ("Matrixes composed of ethylene-vinyl acetate copolymers are useful vehicles for the sustained release of macromolecules such as proteins These polymer systems had uniform drug distribution, and their release kinetics were reproducible."); p. 267 ("Therefore, macromolecules were added to a solution of polymer dissolved in a volatile solvent

(methylene chloride). This mixture, when cast and dried, produced matrixes capable of sustained macromolecular release. . . . The reproducibility of release kinetics for matrixes prepared by low temperature methods was demonstrated for different proteins and for a range of particle sizes and loadings."); p. 268 ("A coating can also be used to control macromolecular release kinetics."); p. 269 ("Clinically, these systems may prove valuable as single-step methods for immunization or for the continuous delivery of insulin and other high molecular weight drugs.").

Aebischer: p. 282-83 ("Chemically inert polymer matrices, allowing controlled release of entrapped macromolecules over long time periods . . . open a new avenue of investigation. . . . The solvents used appear to have no detrimental effects on the biological activity of a number of growth factors."); p. 283 ("Channel Fabrication"); p. 283 (disclosing the use of an impermeable outer coating which results in directional release of the treating factors into the lumen of the device); Table 1; p.286 ("The present study demonstrates that ethylene vinyl acetate copolymer can be fabricated into tubes with adequate physical properties for nerve entubulation and allows the controlled release of macromolecules.").

Langer IX: p.267 ("Two polymers suitable for sustained macromolecular release, poly(hydroxyethyl methacrylate), and alcohol-washed ethylene-vinyl acetate copolymer, were noninflammatory.") ("[W]e provide documentation that two polymers suitable for sustained macromolecular release, poly(hydroxyethyl methacrylate) (polyHEMA) and alcohol-washed ethylene-vinyl acetate copolymer, possess a high degree of biocompatibility in the rabbit cornea."); p.269; Table 1; p.276.

Langer X: p.179-80 ("Although we investigated several polymeric systems, the best results from the standpoint of tissue biocompatibility and long-term release (>100 days) were obtained with ethylene-vinyl acetate copolymer."); p.180 ("Biocompatibility studies"); p.181-87 ("In vitro and in vivo release kinetics"); p.192 ("Possible mechanisms of release of macromolecules") ("The absence of effect of ionic strength (fig7) suggests that osmotic pressure or charge interactions of drug with polymer have negligible roles in affecting release rates."); p. 195-200 ("Here, four studies exploring biomedical uses of these polymer systems are discussed. These include: (1) insulin delivery systems, (2) vehicles for immunization, (3) interferon delivery systems, and (4) systems for delivering anticancer or antiangiogenic macromolecules.").

Langer XI: p.95-96 ("Recent studies in our laboratory have demonstrated, however, that solvent casting of a variety of polymeric materials (ethylene-vinyl acetate copolymer, polyvinylalcohol, poly-2-hydroxymethyl-methacrylate) in the presence of powdered drug permits continuous release of macromolecules for over 100 days.").

Brown: p.1181 ("Macromolecules such as enzymes, antigens, and insulin have been released in biologically active form [from ethylene-vinyl acetate copolymers] for up to 6 months *in vivo*."); p. 1184 ("These data show that *in vivo* release can be accounted for by the same mechanisms operating *in vitro*; this should now make possible the further development and increased use of ethylene-vinyl acetate copolymer drug delivery systems.").

Kost & Langer: p.47-48 ("Bioerodible controlled systems."); p.48-49 ("Applications").

Hsu & Langer: p. 445-46 ("The current study shows the MW of EVAc copolymer is as important as drug loading and drug particle size in affecting the drug release kinetics. A release mechanism, which includes the properties of the polymer carrier, is proposed to serve as a guideline in selecting a suitable EVAc polymer carrier for a particular drug release device."); p.459.

Bawa: p.259 ("For example, EVAc polymers have been used as . . . delivery systems for insulin, interferon, and antigens."); p.263 ("Minimal effects exist due to osmosis or charge interaction of the drug with the polymer."); p.266 ("The data should be useful in the design of release vehicles for various polypeptides, polysaccharides, and other bioactive agents now produced by genetic engineering.").

Leong & Langer: p.202; p.203 ("The two common chemically controlled systems are a biodegradable matrix in which the drug is dispersed, and a polymer-drug conjugate in which the drug molecules are linked to the side chains of the polymer."); p.206-209 (describing use of biodegradable polymers for contraceptive systems); p.210-11 ("Against Ehrlich ascites carcinoma in rats, a sustained release of 5-fluorouracil from poly(ethylenevinylalcohol) is more efficacious than free drug administration."); p.211-14 ("Pendant systems"); p. 214-15 (use of EVAc for hormonal therapy and angiogenesis inhibition); 219-23 ("The clear demonstration of the feasibility [of sustained release of insulin from polymer] was later provided by a study using poly(ethylenevinylacetate) (EVAc).").

Baker: p.14-15 ("Diffusion-Controlled Monolithic Systems"); p.15-16 ("Biodegradable Systems"); 161-65 ("Poly(ethylene vinyl acetate)").

Langer XII: p.162 ("In chemically controlled systems, release is accomplished either by biodegradation of the polymer or by chemical cleavage of the drug from a polymer backbone on which the drug had been bound as a pendant group."); p.163 ("A variety of reservoir and matrix devices are prepared from swollen crosslinked hydrophilic polymers (hydrogels). Most successful devices of this kind are based on poly (2-hydroxyethyl methacrylate) (PHEMA) and related polymers although hydrophilic homopolymers of (poly vinyl 1-2-pyrrolidone) (PNVP), poly (vinyl alcohol) (PVA) and copolymers thereof have been tested with considerable success.") ("Ethylene-vinyl acetate (EVA) copolymers are prepared by emulsion copolymerization of ethylene and vinyl acetate. They are soluble in organic solvents and they can be used to prepare films or rods of dimensional stability and good mechanical strength."); p. 163-64 ("Biodegradable Polymers"); 164-67 (clinical uses for controlled-release polymer systems).

Langer XIII: p.166; p.170 ("Studies have also been conducted to explore numerous applications of these systems. These include release of insulin . . . , anti-calcification agents . . . , interferons . . . , growth factors . . . and inhibitors . . . , and neurologically active agents.").

Chasin: p.43-44 ("In designing a biodegradable system that would erode in a controlled heterogeneous manner without requiring any additives, we have suggested that due to the high liability of the anhydride linkage, polyanhydrides may be promising candidates."); p.45 ("Molding procedures"); p.47-62 ("Kinetics of Drug Release") (describing release of various compounds); p.66-68 (polyanhydride safety and clinical studies).

Langer XIV: p.538-40 (describing polymers used in controlled release systems, including cellulose, poly(glycolic acid) and poly(lactic acid), poly(ortho esters), polyanhydrides, silicone rubber, ethylene-vinyl acetate copolymer, and poly(2-hydroxyethyl methacrylate)); 540-42 (describing clinical uses for controlled release systems).

Brem: p.2 ("The ethylene-vinyl acetate copolymer (EVAc) is an example of a non-biodegradable polymer while poly[bis(p-carboxyphenoxy) propane-sebacic acid] copolymer (PCPP-SA) and the fatty acid dimmer-sebacic acid copolymer (FAD-SA) are examples of biodegradable polymers."); p.3 ("Clinical applications for the EVAc polymer include drug delivery for contraception, insulin therapy, cancer chemotherapy, glaucoma treatment, dental caries prevention, and asthma therapy."); p.4-6 (describing in vivo and clinical studies of PCPP-SA and EVAc based delivery of chemotherapeutic drugs).

Langer XV: p.102 ("Our best long-term release results were obtained with relatively hydrophobic polymers, such as ethylene-vinyl acetate co-polymer or lactic glycolic acid copolymer, using methylene chloride as a casting solvent."); p.105 ("Therefore, we proposed to initiate studies on the development of a new class of bioerodible polymers: polyanhydrides."); p. 109 ("Through the NH₂ groups of lysine, specific amino acid sequences such as arginine-lysine-aspartic acid (RGD) have been chemically coupled to polylactic acid-co-lysine.").

Thompson: p.31-32; p.32 ("In this article, we include hydrolysis and enzymatic degradation under the heading of biodegradative processes."); p. 32-33 ("Collagen is one of the most widely used and best characterized of the natural biomaterials"); p.33 ("Gelatin, cross-linked with formaldehyde, has been studied in vitro as a drug delivery matrix . . ."); p.33-34 ("Starch"); p. 34 ("Furthermore, because of its hydrophilicity, cellulose has been utilized in pharmaceutical formulations to enhance water uptake and improve drug delivery.") ("The degradation of synthetic polymers is, in general, brought about by simply hydrolysis, although in some cases enzymatic processes assist in the degradation mechanism."); p.35 ("Since . . . the degradation characteristics of [poly(glycolic acid)] are predictable and reproducible, PGA has become a material of choice for many proposed applications calling for a synthetic biodegradable polymer.") ("Poly(L-lactic acid)"); p. 36 ("Poly (ε-caprolactone)") ("[Poly(orthoesters)] have therefore been exploited as constant rate drug delivery devices.") ("Poly(anhydrides)"); p.36-41 ("Hydrophobic polymers") ("Poly(ethylene)"); p. 41-44 ("Hydrophilic Polymers") ("Poly(2-hydroxyethyl methacrylate)"); p.44 ("Natural and synthetic biodegradable polymers have been utilized in drug delivery and tissue engineering. Drug delivery systems based on biodegradable polymers facilitate the controlled release of drugs with the concurrent degradation of the polymer.").

Chandrasekaran: p.587 ("The simplest to a bioerodible drug delivery system is to disperse or dissolve the drug in a water-soluble polymer, which will slowly erode in an aqueous medium Another approach involves the synthesis of hydrophobic water-insoluble polymers in which the major fraction of the drug is released by erosion of the polymer matrix . . ."); p.588 ("Hydrophobic polymer solubilization can be achieved as a result of a chemical reaction that takes place at either a pendant group of the polymer or within the polymer backbone. When the reaction is confined to the pendant group, no backbone cleavage takes place, and one of the reaction products is a hydrolytically stable water-soluble polymer. . . . Hydrophobic polymers

can also be solubilized by an ionization reaction of pendant carboxyl groups; drug dissolution and release rate kinetics are obtained from partially esterified copolymers derived from ethylene-maleic anhydride or methyl vinyl ester-maleic anhydride.").

Kim: p194-96; Fig.4; 197-201 ("Drug Diffusion through Polymers"); p.202-204 ("Release Rate from Monolithic Devices"); p.204-206 ("Mechanistic Considerations of Drug Diffusion through Polymer Membranes"); p.215-220 ("Hydrophobic Polymers as Drug Carriers") ("Ethylene-Vinyl Acetate Copolymer (EVA)"); p.220-23 ("The synthesis of biodegradable polymers for controlled drug release is based on different strategies. 1. A degradable polymer medium to which a drug is dispersed. Here drug diffusion through the polymer matrix is influenced by the degradation of the polymeric material. 2. A degradable polymer medium to which a drug is attached through a hydrolytically labile linkage. Drug release is controlled by both hydrolysis of the drug from the polymer and by diffusion of the drug through the polymer matrix."); p.226-28 ("Design of Chemically Bound Polymer-Bioactive Agent (PBA) Systems"); p.228-29 ("Models of Chemically Bound Polymer-Bioactive Agent Systems."); p.229-46 ("Examples of Chemically Bound Polymer-Bioactive Agent Systems").

Dev: Abstract; p. 273 ("The purpose of this study was twofold: first, to test a polymer-coated removable stent system for local delivery of two lipid soluble drugs . . . and second, to compare these two drugs with respect to kinetics of their delivery to the arterial wall with the stent in place and their tissue washout rates after removal of the stent."), ("We used a commercially available biomedical grade polyurethane [as a stent coating]. . . . To study the kinetics of drug delivery, we used two lipid soluble compounds: forskolin and etretinate."), ("Ratio of peak drug levels in the vessel wall to those in the blood was 6,000 for etretinate and 780 for forskolin. . . . Polymer-coated stents could be used for local drug delivery to the vessel wall."); p. 274-75 ("the drug levels [of etretinate] in blood and the distant tissues are extremely low, and the ratio of local to systemic drug levels is very high (~6,000); p. 277 ("This [preferential release of drug into the arterial wall] may reflect slower diffusion of etretinate in the aqueous medium than forskolin or presence of significant tissue binding of etretinate.").

Claim 16 [16A]: The method of claim 15 wherein the placed device substantially restrains at least one type of macromolecule produced by adjacent tissue.

Where Found in the Prior References:

Schwartz '823: Abstract; col. 2:29-40; col. 2:49-53; col. 3:58-61 ("The improvement of the present invention includes applying to the above-mentioned type of stent a flexible or elastomeric polymeric film which extends between the metal elements."); col. 3:64-4:6; col. 4:13-20 ("A flat expandable band can then be provided with a flexible polymeric film. The film can be made from virtually any type of biostable or biodegradable polymer which is suitable for implantation in a human or animal body. For example, the polymer can be a polyurethane, a

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polyester, polylactic acid, a polyamino acid, polyorthoester, polyphosphate ester or composites thereof."); col. 6:17-20; col. 7:25-8:11.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); Fig. 3; col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-33; col. 5:34-6:29; col. 6:37-41; col. 6:41-45 ("Modifications of the polymer coating include a ring that encompasses the proximal portion of the stent, single or multiple strips that cover a portion of the stent, or a polymer coating with perforations."); col. 8:23-25 ("Ethylene vinyl acetate copolymer (EVA) (Catalog #34,691-8) was obtained from Aldrich Chemical Company, Inc. (Milwaukee, Wis.); col. 10:24-33; col. 12:1-6; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow Controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Col. 1:7-10 ("This invention relates generally to expandable intraliminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 1:57-64 ("The invention accordingly provides for a drug loaded stent, comprising an expandable stent structural member, and a planar sheet of polymeric material disposed on the outside of the expandable stent structural member. The polymeric material is bioabsorbable, and is preferably loaded or coated or laminated with a therapeutic agent or drug to reduce or prevent restenosis and thrombosis in the vessel being treated."); col. 1:64-2:2 ("The polymer material can be a thermoplastic or an elastomer, for example, so that the film can stretch or deform radially when the stent structural member is expanded. The film of polymer material can be formed as a solid sheet, or can incorporate holes of various sizes and shapes to promote rapid endothelialization."); col. 4:15-24; col. 4:25-46; col. 4:47-5:3; col. 5:4-9; col. 5:49- 6:25 ("The polymeric material is preferably

selected from thermoplastic and elastomeric polymers. . . . In another currently preferred embodiment, the polymeric material can be ethylene vinyl acetate (EVA) . . ."); col. 6:26-65; col. 7:23-42; col. 7:63-65; col. 8:12-57; col. 9:5-12; col. 10:12-30.

Wolff '208: Col. 2:7-16 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:28-30 ("Controlled release, via a bioabsorbable polymer, offers to maintain the drug level within the desired therapeutic range for the duration of the treatment."); col. 6:59-62 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously. The polymer may be biostable or bioabsorbable. If biostable, the drug would diffuse out of the polymer."); col. 6:64-67; col. 7:59-61; col. 9:23-33 ("That layer may be a simple barrier which limits diffusion of drugs in the polymer. In that event, the smaller molecules could elute out immediately, while larger compounds would not elute until later when the layer has biodegraded."); col. 12:37-40 ("8. The device of claim 1 also comprising a barrier coating of polymeric material on the drug-containing filament to limit the rate of drug elution.").

Berg '354: Page 2:43-54 ("Viewed from a further aspect the invention provides the use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug-eluting surface coating."); p. 2:55-58 ("In the method of the invention there is applied to the body of a stent, and in particular to its tissue-contacting surface, a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance (i.e. a drug) dispersed in the solvent, and the solvent thereafter is evaporated to leave a drug-eluting polymeric surface on the stent."); p. 3:29-31 ("Also, stents made with biostable or bioabsorbable polymers such as poly(ethylene terephthalate), polyacetal, poly(lactic acid), poly(ethylene oxide)/poly(butylene terephthalate) copolymer could be used in the present invention. "); Table 1; p. 4:5-24; p. 6:6-11; p. 6:15; p. 6:24-35; p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Abstract ("A stent made of biodegradable material includes a drug that is released at a rate controlled by the rate of degradation of the biodegradable material."); col. 2:16-17; col. 4:1-5 ("In one embodiment, the main body includes a film that is preferable combined with the plurality of fibers disposed around the main body. The film combined with the plurality of fibers defines the outer surface of the main body."); col. 4:15-16 ("Preferable, the main body of the stent includes a film covering the inner surface."); col. 4:19-22.

Ding '536: Abstract ("The coating includes a relatively thin layer of biostable elastomeric material containing an amount of biologically active material, particularly heparin, dispersed in the coating in combination with a non-thrombogenic surface."); col. 1:24-29 ("The present invention relates generally to providing biostable elastomeric coatings on the surfaces of implants which incorporate biologically active species having controlled release characteristics in the coating particularly to providing a non-thrombogenic surface during and after timed release of the biologically active species."); col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of

biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 5:10-56 ("Polymers generally suitable for the undercoats or underlayers include silicones (e.g., polysiloxanes and substituted polysiloxanes), polyurethanes, thermoplastic elastomers in general, ethylene vinyl acetate copolymers, polyolefin elastomers, polyamide elastomers, and EPDM rubbers. The above-referenced materials are considered hydrophobic with respect to the contemplated environment of the invention."); col. 12:62-13:2; col. 13:13-26; col. 13:37-40; col. 14:5-17; col. 14:22-34.

Dinh '227: Col. 2:51-54 ("To accomplish this while not affecting the strength of the overall fibrin stent structure, a first layer is applied to a stent body, the first layer incorporating a polymer and the therapeutic substance."); col. 2:62-66 ("The inclusion of a polymer in intimate contact with a drug on the underlying stent structure allows the drug to be retained on the stent in a resilient matrix during expansion of the stent and also slows the administration of drug following implantation."); col. 3:10-14; col. 3:25-38; col. 5:3-7; col. 5:44-55; col. 5:56-57; col. 6:13-19 ("In U.S. Pat. No. 4,548,736 issued to Muller et al., a dense fibrin composition is disclosed which can be a bioabsorbable matrix for delivery of drugs to a patent. Such a fibrin composition can also be used in the present invention by incorporating a drug or other therapeutic substance useful in diagnosis or treatment of body lumens to the fibrin provided on the stent."); 6:50-56 ("Alternatively . . . a dense fibrin composition suitable for drug delivery can be made without the use of microcapsules by adding the drug directly to the fibrin followed by compression of the fibrin into a sufficiently dense matrix that a desired elution rate for the drug is achieved."); col. 6:62-67; col. 7:10-13; col. 7:56-64 ("In another embodiment of the invention, the coating of polymer and drug on the stent is achieved by forming a first fibrin layer on the stent body which incorporates the therapeutic substance and then applying a second layer of fibrin."); col. 8:52-60 ("Fig. 2 shows an alternative stent in which a fibrin film has been affixed to the underlying metallic framework by affixing it to the stent . . ."); col. 8:64-9:3; col. 12:24-28; col. 12:38-50.

Domb '055: Abstract ("Devices are provided having a polymer coating incorporating compounds inhibiting inflammation and infection, along with subsequent tissue growth onto and around the device. . . . Preferred polymeric coating are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); col. 1:12-15 ("This invention relates to invasive medical devices for delayed/sustained release of pharmaceutical compositions from a polymer that is coated or incorporated into the devices."); col. 3:54-57 ("In the preferred embodiments, these have utilized bioerodible polymers as the matrix for the drug to be released, usually as a function of diffusion and erosion of the polymer."); col. 4:22-36; col. 5:24-37; col. 5:41-45; col. 5:48-6:1; col. 6:24-26 ("Examples of suitable polymers include ethylene vinyl acetate, polyurethane, silicones, hydrogels, polyurethane, and polyvinyl chloride."); col. 7:10-20; col. 7:40-52; col. 9:15-30; col. 9:55-10:2; col. 10:21-52; col. 10:60-11:11; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue,

wherein said biologically active agent is iodine."); col. 11:36-38 ("The medical device of claim 1, wherein the polymer is selected from the group consisting of polyurethane, ethylene vinyl acetate, silicones, hydrogels, and polyvinyl chloride."); col. 11:39-44; col. 12:11-22; col. 12:23-25; col. 12:26-31; col. 12:32-42.

Fox '096: Abstract ("A method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers, and antimicrobial agents . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 2:48-65; col. 3:55-67 ("The polymeric coating agent component of the coating vehicle of the present invention is selected from the group consisting of biomedical polyurethanes, biomedical silicones, biodegradable polymers and combinations thereof."); col. 19:11-16; col. 31:62-64.

Hunter '981: Col. 1:12-17; col. 3:42-45 ("Within one aspect of the present invention, compositions are provided (anti-angiogenic compositions) comprising (a) an anti-angiogenic factor and (b) a polymeric carrier."); col. 3:53-61; col. 12:23-25 ("As noted above, the present invention provides compositions comprising an anti-angiogenic factor, and a polymeric carrier."); col. 16:31-56; col. 17:63-18:7 ("[T]he anti-angiogenic compositions of the present invention may be formed as a film. . . . Such films are preferably flexible with a good tensile strength . . . and has controlled permeability."); col. 22:3-7; col. 22:54-58; col. 47:58-49:7; col. 52:4-8; col. 69:19-62; col. 84:62-86:24; 86:56-59; col. 87:11-22; col. 88:19-26.

Kowligi '782: Abstract ("The elastomeric coating is made of polyurethane or another biocompatible non-porous elastomers and precludes tissue ingrowth into the outer cylindrical wall, minimizes suture hold bleeding, and increases suture retention strength, while reducing the incidence of serous weepage."); col. 1:18-26; col. 2:15-20; col. 2:38-47; col. 2:53-59; col. 3:27-37; Fig. 1; Fig. 2; Fig. 3; col. 2:60-67 ("PTFE tube 32 includes an inner cylindrical wall and an opposing outer cylindrical wall. As shown in Fig. 2, outer cylindrical wall 36 is coated entirely around its circumference by a uniformly thick coating of a biocompatible elastomer."); col. 3:27-38; col. 4:16-27 ("In regard to elastomeric coating 38 shown in Fig. 2, such elastomeric coating is selected to be a biocompatible elastomers and may be selected from the group consisting of medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers."); col. 4:37-39 ("The elastomeric coating should also be sufficiently non-porous to preclude serous weepage and inhibit tissue ingrowth therethrough."); col. 5:4-7; col. 7:49-8:9; col. 8:38-44; col. 9:65-10:6; col. 10:18-24; col. 10:33-42; col. 10:43-50; col. 10:51-59; col. 10:60-67.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic

article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 2:16-35; col. 2:40-50; col. 3:8-12; col. 3:29-32; col. 3:33-49; col. 3:55-61 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); col. 7:29-32; col. 7:38-41; col. 10:57-64; col. 11:49-51; col. 11:65-12:13; col. 12:43-64; col. 13:13-19.

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p. 3:10-31 ("Upon long-term exposure of a prosthetic article to physiological conditions, the biologically active compound is slowly released from the treated polymer."); p. 4:2-12; p. 6:21-28 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility characteristics so as to enable the application of a stable coating onto substrate (i.e., the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected."); claim 1:1-14; claim 8:1-5; claim 10:1-3; claim 11:1-13; claim 22; claim 23:1-14; claim 19:4-31.

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8.

Myler '563: Col. 2:10-13; col. 3:13-15; col. 3:52-54; col. 4:30-43 ("In a preferred embodiment, the interior and exterior walls of stent 10 are enclosed in a thin polymeric envelope. . . . Suitable envelope materials include elastic materials such as latex and others that can be readily selected by one of skill in the art."); col. 5:1-16; col. 5:39-41 ("For the above reasons, even the expanded pores for drug delivery should be small enough to maximize or prevent cell penetration, but large enough for drug delivery."); col. 12:11-13; col. 12:19-23; col. 12:28-33 ("Suitable materials include elastomeric polymers or natural rubber (latex). . . . Polymeric stents can be provided with relatively fluid impenetrable walls, or porous walls such as to allow drug delivery, as will be apparent to one of skill in the art."); col. 12:63-65 ("Suitable coating materials include elastic materials such as polyethylene or PET or other materials that can be readily selected by one of skill in the art."); col. 18:51-19:9; col. 19:18-30; col. 19:31-32; col. 19:61-63; col. 20:33-49; col. 20:51-57.

Palmaz '417: Col. 6:66-68; col. 11:3-14 ("Examples of a suitable biologically compatible coating would be porous polyurethane, Teflon™ or other conventional biologically inert plastic materials."); col. 11:26-31 ("Examples of biologically compatible coatings would include coatings made of absorbable polymers such as those used to manufacture absorbable sutures. Such absorbable polymers include polyglycoides, polyacoides, and copolymers thereof.").

Tice '330: Col. 3:20-33 ("Suitable wall forming materials include polystyrene, ethylcellulose, cellulose acetate, hydroxyl propylmethylcellulose phthalate, cellulose acetate, dibutylaminohydroxypropyl ether, polyvinylbutyral, polyvinyl formal, poly(meth)acrylic acid ester, polyvinylacetal-diethylamino acetate, 2-methyl-5-vinyl pyridine methacrylate-methacrylic acid copolymer, polycarbonate, polyesters, polypropylene, vinylchloride-vinylacetate copolymer, polysaccharides, glycerol distearate, and the like. A preferred group of polymeric wall forming materials includes those which are biodegradable such as aliphatic polyesters including polylactide, polyglycolide, polycaprolactone and copolymers thereof."); col. 8:38-51.

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); col. 3:7-18; col. 3:56-63; col. 4:31-34 ("The outer membrane surface is nonporous, while porous inner membrane surface allows for the diffusion therethrough of active factor 26."); col. 5:18-28 ("In a preferred embodiment of the invention, the outer surface of the membrane is impermeable to solutes of any size, while the inner membrane surface contains pores [that] enable the active factors to diffuse out of the membrane and into the lumen of the channel."); col. 6:17-22 ("The layering procedure allows deposition of an impermeable coat on the outer surface of the device, insuring that the active factors incorporated into the membrane walls will be inhibited from diffusing through the external surface, and will diffuse only through the inner membrane surface into the lumen of the channel."); 6:54-61; col. 9:18-10:3.

Folkman '560: col. 2:43-68 ("A biocompatible plastically deformable polymer matrix . . . substantially impermeable to a macromolecule"); col. 3:18-23 ("The polymer matrixes, which are suitably used in the present invention, are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:36-51 ("Typical polymeric material suitable for forming the matrix . . . include . . . alkylene-vinyl acetate copolymers . . . crosslinked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:52-4:26 ("In the presently preferred embodiment the polymeric materials useful for forming the matrix are the ethylene vinyl ester copolymers of the general formula . . ."); col. 11:56-12:20.

Cohen '496: Col. 3:26-45 ("The polymer matrices . . . are biocompatible in the environment of use, plastically deformable, have limited water sorptivity, and they are substantially impermeable to the passage of biologically active macromolecular materials in admixture therewith."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:46-63 ("Typical polymeric material suitable for forming the matrix . . . are naturally occurring and synthetic commercially available polymers [including] alkylene-vinyl acetate copolymers . . . cross linked homo- and co-polymers of polyvinyl acetate . . ."); col. 3:65-4:39 ("In a presently preferred embodiment, the polymeric materials useful for forming the matrix are the ethylenevinyl ester copolymers of the general formula . . ."); col. 9:40-10:17; col. 10:18-32.

Schiraldi '243: Col. 1:8-21 ("The extruded film drug delivery system of the present invention, which has incorporated therein the medicament to be dispensed, is so thin and flexible

when wet as to be unobtrusive to the patient after it has been properly positioned and placed in the mouth."); col. 1:58-60; col. 2:30-51; col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 9:36-55; col. 10:12-18.

Valentini '029: Abstract ("Medical devices employing semipermeable materials, such as acrylic copolymers, polyurethane isocyanate, and other biocompatible semipermeable polymers, are disclosed for use as guidance channels in regenerating nerves. . . . The guidance materials are chosen such that they are capable of allowing the diffusion of nutrients and other metabolites to the regenerating nerve site while excluding fibroblasts and other scar-forming cells."); col. 2:29-57 ("It has been discovered that the repair of severed or avulsed nerves can be greatly enhanced by the use of selectively permeable polymeric materials as nerve guidance channels. . . . The devices can be formed from various polymeric materials, such as acrylic copolymers, polyvinylidene fluoride or polyurethane isocyanate Preferable, the materials allow passage therethrough of solutes having a molecular weight of about 100,000 daltons or less. . . . The nerve guidance channels of the present invention are also preferably designed to retain nerve growth factors secreted at the anastomatic site or seeded therein, as well as retain any luminal matrix material placed inside the guidance channels."); col. 2:58-3:14; col. 4:46-59; col. 5:13-32 ("The success rate and quality of peripheral nerve regeneration was dramatically enhanced through the use of a semipermeable material."); col. 5:42-6:12 ("The permselective characteristics of the inner membrane allow the exchange of nutrients, while concentrating growth factors released by the nerve and excluding scar-forming cells."); col. 6:14-24; col. 6:31-42.

Greco '135: Col. 3:48-4:1 ("These devices will consist of organic polymers and/or metallic materials including: . . . polyethylene . . . elastomeric organosilicon polymers, such as polysiloxanes, e.g. Silastic ®").

Aebischer '627: Col. 3:57-4:3 ("The polymeric insert includes pores having a molecular weight exclusion of from about 1 kD to about 1,000 kD, but preferably from about 25kD to about 100 kD."); col. 4:11-27 ("The terms 'semipermeable' is used herein to describe biocompatible membranes that allow the diffusion therethrough of molecules having a relatively low molecular weight, while excluding the passage of those having a relatively high molecular weight. . . . The semipermeable membrane can me made of various polymeric compositions such as polyvinylchloride, polyacrylonitrile, polyvinylidene fluoride, polysteyrene, polymethylmethacrylate, polysulfone, and acrylic copolymers."); col. 7:57-8:14 ("In this embodiment, a semi-permeable membrane functions as a protective cell culture device for the neurotransmitter-secreting cells. The pores of the membrane should be large enough to enable the exchange of metabolites with body fluids, and to permit the diffusion therethrough of neurotransmitter produced by the cells therein, but are small enough to bar the passage therethrough of larger elements deleterious to the cells."); col. 13:31-48; col. 13:66-68; col. 14:1-2; col. 14:22-28; col. 14:54-56.

Wood '066: Abstract ("A controlled-release bandage containing therapeutic agents in a poly(vinyl alcohol) cryogel is disclosed. The bandage may include . . . hydrophobic particles to further insure controlled and constant release of therapeutic agents."); col. 2:56-66; col. 23:4-11.

Strecker '746: Abstract ("It has a lining of a wrapping material that deforms plastically without fissuring as it expands from the state with the narrow lumen to the state with the wide lumen. . . . The lining is impregnated with at least one medication that will gradually and preferably at a uniform rate be released to the patient once the prosthesis is in place."); col. 1:63-2:2; col. 2:12-15 ("The present invention on the other hand exploits a wrapping material that plastically deforms as it expands . . ."); col. 2:21-38; col. 2:59-64; col. 3:7-16; col. 3:27-33 ("The lining can to advantage be made of polymers or compounds thereof."); col. 3:51-62; col. 3:51-62; col. 5:49-54 ("The thread itself in an endoprosthesis of the type illustrated in Fig. 3 can also be wrapped in a coat of medicated and biodegradable wrapping material. . . . The prosthesis can of course alternatively be enclosed in a flexible-tubular coat."); col. 6:50-55; col. 6:59-62; col. 7:16-35; col. 8:4-8; col. 8:19-10:19.

Lambert '246: Abstract ("Thus, a polyurethane coating is applied to a prosthetic article, the coating then swelled . . . so that substantial quantities of biologically active compounds can be incorporated within the interstices of the polymer."); col. 2:15-34; col. 2:40-49; col. 2:53-65; col. 3:55-4:35 ("Polyurethanes employed in the practice of the present invention typically have certain flexibility, strength and biocompatibility to as to enable the application of a stable coating onto substrate (i.e. the coating will be able to withstand certain handling, deformation, abrasion, exposure to various environments, and the like, to which the resulting article will be subjected)."); col. 10:45-67; col. 11:34-59; col. 12:15-41.

Bellamkonda '029: Abstract ("A nerve guidance channel for use in regenerating severed nerve is prepared containing a tubular semi-permeable membrane having openings adapted to receive the ends of a severed nerve, and an inner lumen containing the matrix having an adhesive peptide fragment through which the nerve can regenerate."); col. 2:65-3:5 ("This invention provides a three-dimensional hydrogel based, biosynthetic, extracellular matrix (ECM) equivalent, and method of making same. Agarose matrices having chemistry amenable to derivitization with various ECM adhesive peptides and proteins, are preferred in forming the 3-D hydrogel substrates of this invention. These biologically active 3-D templates may be useful in facilitating tissue regeneration or replacement."); col. 4:9-14; col. 4:21-39 ("Any suitable hydrogel may be used as the substrate for the bioartificial extracellular matrices of this invention."); col. 4:48-57; col. 5:10-14 ("Several physical properties of the hydrogel matrices of this invention are dependent on gel concentration. Increase in gel concentration may change the gel pore radius, morphology, or its permeability to different molecular weight proteins."); col. 7:13-25; col. 10:28-40 ("Permeable channels with a molecular weight cut-off of 50,000 daltons allowed regeneration of nerves in a mouse sciatic nerve model."); col. 10:41-63; col. 10:64-11:13; col. 12:13-16 ("Preferably the permeable membrane is fabricated to be impermeable to some of these substances so that they are retained in the proximity of the regenerating nerve ends."); col. 12:17-25 ("Briefly, various polymers and polymer blends can be used to manufacture the nerve guidance channel."); col. 12:42-49; col. 19:7-16; col. 23:54-24:55.

Dayton '382: Abstract ("The device comprises a stent which is formed from metal or polymers into a predetermined shape which includes a plurality of holes . . . to provide a desired bending modulus. The stent is then coated with a polymer . . . which contains a bioactive substance which achieves an equilibrium with the surrounding body tissues or fluids, with the equilibrium being controlled by charge distribution, concentration and molecular weight of the bioactive substance in relation to the pore size of the polymeric carrier for controlled prolonged release of said bioactive substance."); col. 3:62-4:4:17 ("Among these polymers are polymers having a microporous structure, such as . . . biodegradable polylactic acid polymers, polyglycolic acid polymers . . ."); col. 4:24-33 ("A bioactive substance is preferably admixed in the polymer for elution from the microporous structure of the stent or coating on the stent after implantation. The rate of elution of the bioactive substance is controlled by selecting a pore size for microporous structure . . ."); col. 4: 42-50; col. 4:54-5:3; col. 6:64-7:7 ("The polymer should have a microporous structure with a predetermined pore size."); col. 8:19-33; col. 8:42-59; col. 8:66-9:5; col. 10:1-2.

Burt '036: p. 4:19-33 ("Similarly a wide variety of polymeric carriers may be utilized, representative examples of which include poly(ethylene-vinyl acetate) . . . and copolymers of polylactic acid and polycaprolactone."); p.10:17-25; p.14:9-27 ("As noted above, anti-angiogenic compositions of the present invention comprise an anti-angiogenic factor and a polymeric carrier. In addition to the wide array of anti-angiogenic factors and other compounds discussed above, anti-angiogenic compositions of the present invention may include a wide variety of polymeric carriers, including for example both biodegradable and non-biodegradable compositions."); p.21:2-4; p.21:35-22:1 ("Within preferred embodiments of the invention, the composition should firmly adhere to the stent during storage and at the time of insertion, and should not be dislodged from the stent when the diameter is expanded from its collapsed size to its full expansion size."); p.51:1-52:35.

Goldin '568: Col. 1:43-62 ("Release by controlled diffusion may be accomplished by means of containment of the therapeutic agent within a substrate whose small pore size and/or tortuosity of diffusion path thereof limits the diffusion of said agent through the substrate. . . . The therapeutic agent can be incorporated within the diffusion-limiting substrate Materials that have been used to fabricate diffusion-controlled slow release devices . . . include ethylene-vinyl acetate copolymers . . . and hydroxylalkyl methacrylates."); col. 2:24-29 ("Microporous membranes for release of proteins by controlled diffusion have been fabricated from ethylene vinyl acetate (EVA), and said membranes have been used in vivo in a manner which demonstrates their therapeutic potential."); col. 5:28-34 (" . . . underlayment material of controlled pore size can be created and used to fabricate a device of optimal porosity . . . and accessibility of the releasable macromolecule to biological material at or beyond the membrane's external surface . . ."); Fig. 1A; col. 11:58-12:14; col. 13:53-65; col. 14:1-28; col. 14:66-15:67; col. 31:57-32:7 ("The device of claim 1 wherein said microporous underlayment comprises a polymer."); col. 32:16-22.

Palmaz '665: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3:47-51 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5: 30-

32 ("FIGS. 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon."); Figures 5 and 6.

Palmaz '337: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3:52-56 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5: 19-21; Figures 5 and 6; col. 8: 28-32; col. 9: 24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '762: Col. 10:28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials."); col.3:65-4:2 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 9: 20-25; col. 10: 28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Zaffaroni '254: Abstract ("The wall is formed in at least a part of a microporous material..."); col. 1: 19-23 ("The wall of the device is comprised in at least a part of a microporous material..."); col. 3: 5-10; col. 3: 48-53; col. 4: 47-54 ("Wall 11 is formed of a microporous material the micropores 15 of which contain a drug release rate controlling medium, not shown, permeable to the passage of drug, as by diffusion, or by convection,, or by a concurrent operation of both, but the rate of passage of the drug through the medium in the micropores is lower than the rate of passage of drug through the solid drug carrier."); col. 5: 3-11.

Aebischer: p. 283 (disclosing impermeable polymer layer that restricts passage of treating material).

Dev: p. 273 ("We used a commercially available biomedical grade polyurethane Tecoflex is a biocompatible, flexible, and an elastic membrane-forming polymer.").

Claim 17 [17A]: The method of claim 15
whereby the device is placed adjacent to the
tissue in association with a stabilizing device.

Where Found in the Prior References:

C-484

Schwartz '823: Abstract ("A radially expandable stent for implantation within a body lumen having a generally cylindrical body with open proximal and distal ends, the cylindrical body comprising a plurality of metal elements joined to allow flexing of the cylindrical body along the longitudinal axis of the body whereby the stent can conform to a curved body lumen and a polymeric film extending between the metal elements of the stent. The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen."); Figs. 6-9, 13, 15; col. 2:37-40 ("In essence, this improvement makes it possible to provide a stent able to support body lumens and conform to curves or irregularities in body lumens."); col. 2:44-54 ("The composite stent of the present invention can be delivered to the site of the occlusion by catheter and expanded conventionally, causing the film to expand or open radially along with the metallic elements of the stent and to be brought into contact with the body lumen. The polymeric film is flexible and preferably an elastic or stretchable film that is capable of conforming to the movement of the metallic stent elements when expanded into contact with a body lumen."); col. 2:59-68 ("Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent can also incorporate therapeutic substances in or on the polymeric film such as those disclosed in published International Patent Application WO 91/12779 'Intraluminal Drug Eluting Prosthesis', which is incorporated herein by reference. The stent can then be used to administer such therapeutic substances to the vessel and to the bloodstream for the prevention of thrombosis or prevention of restenosis in the vessel."); col. 3:48-54; col. 3:58-4:6 ("The improvement of the present invention includes applying to the above-mentioned type of stent a flexible or elastomeric polymeric film which extends between the metal elements."); col. 4:20-24 ("The term 'film' or 'flexible film' herein therefore means that, as applied to the metal stent elements in a thin cross section, the film is capable of flexing or stretching to preserve the radial expandability and axial flexibility of the implanted stent."); col. 5:59-6:2; col. 6:17-38 ("As shown in Fig. 9, with the angioplasty procedure completed, balloon is deflated and withdrawn leaving stent firmly implanted within vessel with the film held in contact with the vessel."); col. 6:40-43; col. 6:49-52 ("As shown in Fig. 13, the stent can be delivered to the body lumen and expanded (e.g. by use of a balloon catheter) into contact with the body lumen."); col. 6:59-62 ("The flexible film can be applied as a sheath to the metal stent elements after which the stent can be compressed, attached to a catheter, and delivered through a body lumen to a desired location."); col. 6:62-68 ("Once in the desired location, the stent can be released from the catheter and expanded into contact with the lumen as shown in Fig. 15 where it can conform to the curvature of the body lumen. The flexible film is able to form folds which allow the stent elements to readily adapt to the curvature of the body lumen."); col. 8:27-32.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); Fig. 3; col. 4:12-14 ("The present invention satisfies this need by providing a separate sleeve to encompass the stent and serve as a local drug delivery device to prevent thrombosis."); col. 4:53-55 ("The present invention satisfies this need by providing a separate sleeve to encompass a stent to locally administer drugs to prevent

restenosis."); col. 4:58-68 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug. . . . Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); col. 5:26-33; col. 6:37-45 ("The invention also provides a kit comprising the sheath and a stent. Also disclosed is a device comprising a stent encompassed by the sheath. The initial prototype is a sleeve of polymer, either degradable or non-degradable, that covers the entire stent (Fig. 3). Modifications of the polymer coating include a ring that encompasses the proximal portion of the stent, single or multiple strips that cover a portion of the stent, or a polymer coating with perforations."); col. 6:49-59 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject. Finally, the invention provides a method of inhibiting vascular cell growth in a subject comprising inserting a stent encompassed by a sheath containing an inhibitor of vascular cell growth into a vessel of the subject."); col. 7:55-59 ("Further, local delivery of growth factors or inhibitors by this method can be performed. For example, one can develop laminate films which deliver growth inhibitors abluminally, while delivering other agents lumenally to anticoagulate the blood flow surface); col. 8:58-60; col. 9:12-16; col. 9:67-10:3 ("In addition, our sleeve device enables the targeting of drugs to be released not only into the lumen to prevent thrombosis, but also the release of drugs into the arterial wall to inhibit the cellular proliferative response."); col. 10:24-33 ("In combination, a hollow tubular stent having a predetermined length and a separate sheath removably encompassing at least a portion of said hollow tubular stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug."); col. 12:9-12; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow Controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Col. 1:7-10 ("This invention relates generally to expandable intraliminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:12-20 ("Stents are typically implanted within a vessel in a contracted state and expanded when in place in the vessel in order to maintain patency of the vessel to allow fluid flow through the vessel. Ideally, the

implantation of such stents is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 1:50-56; 1:57-64; col. 2:3-55; col. 3:30-32; col. 3:36-39 ("Fig. 9 is a plan view of a sheet of polymeric material in another alternative embodiment including elastic strips for securing the polymeric material wrapped around a stent structural member;"); col. 3:40-41; col. 3:51-54 ("Fig. 14 is a plan view of a sheet of polymeric material in a further alternative embodiment including attachment tabs for securing the polymeric material to a stent structural member;"); Fig. 15; col. 3:55-57 ("Fig. 15 is an elevational view of a drug loaded stent wrapped with the sheet of polymeric material of Fig. 14 and mounted on a balloon dilation catheter for delivery."); Fig. 16; col. 3:58-60 ("Fig. 16 is an enlarged partial sectional view of the drug loaded stent of Fig. 15 showing the sheet of polymeric material wrapped around a slotted tube stent structural member."); col. 4:15-24; col. 4:25-46 ("The planar sheet of polymeric material is preferably adapted to uncoil and expand to match the expansion of the stent structural member. . . The stent can be mounted on a balloon dilatation catheter, for deployment of the stent in the vasculature of the patient."); col. 4:47-5:3; col. 5:4-9; col. 5:15-17; col. 5:18-25; col. 5:25-31; col. 5:36-48 ("A representative stent structural member with which a sheet of polymeric material can be combined according to the principles of the invention is illustrated in Fig. 8."); col. 6:26-65 ("In another currently preferred embodiment illustrated in Figs. 9-13, the stent that can be drug loaded comprises a stent metal structural member, such as the stent structural member illustrated for example in Fig. 8, and a planar sheet or film of polymeric material, preferably including a plurality of apertures, as will be further explained below."); Fig. 8; col. 7:42-53; col. 7:56-62 ("The elastic material attached over the coil of polymeric material helps keep the coil of drug loaded material snug on the stent structural member before it is expanded, and guides its linear expansion during inflation of a balloon dilatation catheter used for deployment of the stent and polymeric drug loaded material in the vasculature or other body lumen of a patient."); col. 8:1-57; col. 9:12-18; col. 9:19-22; col. 9:63-67; col. 10:12-30.

Wolff '208: Abstract; col. 1:11-13; 1:52-54 ("The invention provides prostheses which may be inserted into a lumen of a body and fixed to the lumen wall adjacent an area needing treatment."); col. 1:63-66; col. 2:7-9 ("The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action."); col. 2:12-16 ("In all cases, the prostheses of the invention require the presence of an elutable drug compounded to the prosthesis itself. With conventional metal stents, the invention requires a drug-carrying coating overlying at least a portion of the metal."); 2:25-27; col. 6:36-38; 6:56-58 ("The stent shown in Figs. 2 and 4 is a metallic malleable design which may be forced against a lumen wall by a balloon catheter

which fixes it into position."); col. 6:59-62 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously."); col. 9:39-42 ("The device is fixed into place either by radial expansion in devices such as shown in Fig. 1 or are deformed by a balloon catheter in the case of devices in accordance with Fig. 2."); col. 9:60-10:3 ("In yet another embodiment of the invention, a purely polymeric prosthesis such as that having the configuration shown in Fig. 1 can be combined with an expandable metal stent to provide additional support for the prosthesis. . . . By including a metal stent within the lumen of the polymeric prosthesis, the polymeric prosthesis is effectively held against the wall of the body lumen by the strength of the metal stent."); col. 10:3-45 ("The stents are arranged on the distal end of the catheter such that the catheter can provide remote, transluminal deployment of the stents, with the metal stent inside the polymeric stent, from an entry point into a selected portion of the body lumen to be treated and also remote actuation of an expansion mechanism from the proximal end of the catheter. The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen."); col. 10:46-59; col. 10:59-11:20; col. 11:50-53; col. 12:1-15.

Berg '354: Page 2:3-4 ("This invention relates to intravascular stents for treatment of injuries to blood vessels and particularly to stents having a framework onto which a therapeutic substance or drug is applied."); p. 2:14-18 ("The stent is typically inserted by catheter into a vascular lumen and expanded into contact with the diseased portion of the arterial wall, thereby providing internal support for the lumen. Examples of stents which have been successfully applied over a PTCA balloon and radially expanded at the same time as the balloon expansion of an affected artery include the stents disclosed in US-A-4733665 (Palmaz), US-A-4800882 (Gianturco) and US-A-4886062 (Wiktor) which are incorporated herein by reference in their entirety."); p. 2:43-53 ("Viewed from a further aspect the invention provides the use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug-eluting surface coating."); p.2:55-3:7; p. 3:16-18; p. 3:31-34; p.3:54-55 ("The solution is applied to the stent and the solvent is allowed to evaporate, thereby leaving on the stent surface a coating of the polymer and the therapeutic substance."); p. 6:6-11; p. 6:17-19; p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Buscemi '450: Col. 3:14-15 ("The stent strengthens an area of the vessel that is in contact with the stent."); col. 3:21-25 ("The tubular main body includes an outer surface and inner surface. The outer surface of the main body faces an inner surface wall of the vessel. The inner surface of the stent faces a stream flowing through the lumen as shown in cross section in Fig. 2."); col. 4:61-64 ("The stent is secured by releasing the stent from compression so that the stent can radially spring out to abut against the inner surface wall of the vessel."); col. 6:49-52; col. 7:27-29; col. 8:9-11.

Ding '536: Col. 1:24-32 ("The present invention relates generally to providing biostable elastomeric coatings on the surfaces of implants which incorporate biologically active species having controlled release characteristics in the coating particularly to provide a non-thrombogenic surface during and after timed release of the biologically active species. The invention is particularly described in terms of coating on therapeutic expandable stent prostheses for implantation in body humans, e.g., vascular implantation."); col. 3:19-27 ("Accordingly, it is primary object of the present invention to provide a coating and process for coating a stent to be used as a deployed stent prostheses, the coating being capable of effective controlled long-term delivery of biologically active materials."); col. 5:38-40; col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 12:20-23 ("It will be appreciated that the mechanism of incorporation of the biologically active species into a thin surface coating structure applicable to a metal stent is an important aspect of the present invention."); col 13:13-26 ("A medical device having at least a portion which is implantable into the body of a patient, wherein at least a part of the device portion is metallic and at least part of the metallic device portion is covered with a coating for release of at least one biologically active material . . .").

Dinh '227: Col. 1:32-35 ("The stent is typically inserted by catheter into a vascular lumen told [sic] expanded into contact with the diseased portion of the arterial wall, thereby providing mechanical support for the lumen."); 3:41-46 ("Fig. 1 is an elevational view of a balloon catheter with a metallic stent including a fibrin coating according to the present invention. . . ."); Fig. 1; Fig. 2; col. 3:64-65; Fig. 10; col. 5:3-7; col. 6:56-67 ("The inclusion of a polymer in intimate contact with a drug on the underlying stent structure allows the drug to be retained on the stent in a resilient matrix during expansion of the stent and also slows the administration of drug following implantation."); col. 7:10-21; col. 7:56-64 ("In another embodiment of the invention, the coating of polymer and drug on the stent is achieved by forming a first fibrin layer on the stent body which incorporates the therapeutic substance and then applying a second layer of fibrin."); col. 8:26-43 ("The stent can also have underlying polymeric or metallic structural elements onto which the fibrin is applied or the stent can be a composite of fibrin intermixed with a polymer."); col. 8:49-60; col. 9:18-24 ("The stent is then delivered through the body lumen on the catheter to the treatment site where the stent is released from the catheter to allow it to expand into contact with the lumen wall."); col. 9:49-50 ("The resulting fibrin stent includes the stent embedded in a very thin elastic film of fibrin."); col. 9:59-63; col. 10:29-31 ("The metal stent portion mentioned above may be eliminated to make a fibrin tube which can be placed on a balloon catheter and expanded into place in a body lumen."); col. 11:60-62 ("It will be readily appreciated that a fibrin stent with an attached metallic framework can be readily provided by this molding method."); col. 12:24-28.

Domb '055: Abstract ("Preferred polymeric coatings are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); col. 1:12-15 ("This invention relates to invasive medical devices for delayed/sustained release of pharmaceutical compositions from a polymer that is coated or incorporated into the devices."); col. 4:25-36; col. 5:24-27 ("Devices are provided having a polymer coating incorporating compounds inhibiting inflammation and

infection, along with subsequent tissue growth onto and around the device."); col. 5:27-33; col. 5:35-38; col. 5:46-48; col. 5:49-54; col. 5:60-6:1; col. 6:3-18; col. 7:10-20; col. 7:40-52; col. 9:15-30; col. 9:55-10:2; col. 10:21-52; col. 10:60-11:11; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device, the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Col. 1:33-36 ("In addition, antimicrobial compositions useful as coatings for medical devices or for forming the device itself are disclosed . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 2:48-65; Col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages."); col. 16:16-23 ("The catheter was dipped in the coating vehicle while the vehicle was being continuously agitated to insure a uniform suspension. The coated catheter was the dried. A tightly adherent coating on the catheter was thus provided."); col. 19:11-16; col. 22:31-37; col. 30:49-53; col. 36:65-37:7.

Hunter '981: Col. 1:12-17 ("The present invention relates generally to compositions and methods for treating cancer and other angiogenic-dependent diseases, and more specifically, to compositions comprising anti-angiogenic factors and polymeric carriers, stents which have been coated with such compositions, as well as method for utilizing these stents and compositions."); col. 4:20-23; col. 4:24-38; col. 4:38-41; col. 5:1-6; col. 5:14-16; col. 5:17-22; col. 5:28-32; col. 16:31-56; col. 22:3-7 ("As noted above, the present invention also provides stents, comprising a generally tubular structure . . . the surface of which is coated with a composition as described above."); col. 22:23-39 ("Representative examples of stents include those described in . . ."); col. 22:40-64 ("Stents may be coated with anti-angiogenic compositions or anti-angiogenic factors of the present invention in a variety of manners, including for example: (a) by directly affixing to the stent an anti-angiogenic composition (e.g., by either spraying the stent with a polymer/drug film, or by dipping the stent into a polymer/drug solution) . . . (d) by inserting the stent into a sleeve of mesh which is comprised of or coated with an anti-angiogenic composition . . ."); col. 23:6-12; col. 23:30-31; col. 23:46-51; col. 24:45-51; col. 24:66-25:5; col. 25:24-29; col. 25:48-54; col. 26:24-29; col. 52:4-8; col. 69:22-26 ("In this study, strecker stents were coated with an EVA polymer containing paclitaxel at concentration of 33%, 10%, and 2.5% and were tested for their ability to inhibit angiogenesis on the CAM."); 86:56-59; col. 87:11-22; col. 88:19-26.

Kowligi '782: Abstract ("A non-porous coated PTFE graft includes a PTFE tube having a conventional porous inner cylindrical wall and a non-porous elastomeric coating applied over at least a portion of the outer cylindrical wall of the PTFE tube to render such portion of the outer cylindrical wall non-porous."); Figs. 2, 3; col. 1:18-41; col. 2:38-47; col. 2:53-67; col. 3:7-12; col. 3:27-37; Col. 2:60-67 ("PTFE tube 32 includes an inner cylindrical wall and an opposing outer cylindrical wall. As shown in Fig. 2, outer cylindrical wall 36 is coated entirely around its circumference by a uniformly thick coating of a biocompatible elastomer."); col. 5:4-7; col. 5:16-21; 10:18-67.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 2:29-31; col. 3:49-53; col. 3:54-61; col. 5:57-61; col. 7:55-58; col. 8:1-6; col. 11:52-56 ("The method in accordance with claim 1, wherein the substrate is selected from the group consisting of a metallic stent, a heart valve, a metallic prosthesis, a prosthetic joint, a pacemaker, a catheter, a balloon coating, an ocular implant and a contact lens").

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p. 3:24-27; p. 10:17-21; p. 13:20-24; claim 8 ("The method according to claim 1, wherein the substrate is selected from a metallic stent, a heart valve, a metallic prosthesis, a prosthetic joint, a pacemaker, a catheter, a balloon coating, an ocular implant or a contact lens").

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8; p. 2:29-30; p. 3:11-13.

Myler '563: Col. 2:13-15; col. 4:30-43 ("In a preferred embodiment, the interior and exterior walls of stent 10 are enclosed in a thin polymeric envelop."); col. 3:34-37; col. 4:44-52 ("The envelope may be produced, for example, by inserting the stent into a preformed tubular envelope having one open end and sealing the envelope closed, or other techniques within the skill in the art."); col. 4:53-56; col. 5:1-16; col. 5:50-54; col. 10:12-14; col. 10:56-61; col. 11:63-65; col. 12:63-13:1; col. 13:5-17.

Palmaz '417: Col. 4:25-37; col. 11:3-8 ("With reference now to Figs. 5 and 6, prostheses, or grafts of the type previously described in connection with Figs. 1A and 1B are shown, and the tubular members of grafts, or prostheses, have a biologically inert or biologically compatible coating placed upon wall surfaces of tubular shaped members."); col. 13:51-53 ("The method of claim 1, wherein at least one prosthesis is provided with a biologically compatible coating on the outer surface of the prosthesis.").

Aebischer '486: Abstract ("In one aspect of the invention, the membrane has an impermeable, outer membrane surface and a porous, inner membrane surface through which the active factor can diffuse and which defines the boundary of a lumen through which said nerve may regenerate."); Figs. 1 and 2; col. 9:18-10:3.

Strecker '746: Abstract; col. 1:63-2:2; col. 2:12-15 ("The present invention on the other hand exploits a wrapping material that plastically deforms as it expands and accordingly exerts no restoration force on the stent, ensuring persistent expansion."); col. 2:21-32 ("This embodiment has a wrinkled lining around the as yet unexpanded stent."); col. 2:33-38; col. 2:39-46; col. 2:47-53; col. 2:59-64; col. 2:65-3:4 ("[T]he lining can be a flexible tubular membrane or sleeve wrapped around the prosthesis and secured."); col. 3:63-4:31; col. 5:18-20; col. 5:34-41; col. 6:30-64; col. 7:16-35; col. 7:48-65; col. 8:4-9; col. 8:19-10:19; Figs. 4, 7, 8.

Schiraldi '243: Col. 2:52-63 ("The extruded film of the present invention must have at least one bioadhesive layer, but may also have a reservoir layer and/or an outer protective barrier membrane layer. When properly formulated and fabricated, these films will adhere to wet mucosal surfaces, provide a protective barrier for injured tissue and deliver controlled/sustained dosages to the infected areas. The film may be designed for localized drug delivery (i.e., the periodontal pocket, an aphthous lesion, or may allow diffusion of the drug into the oral cavity."); col. 3:3-10 ("An example of a localized application of medication would be in the treatment of aphthous lesions. A laminated two layer film with benzocaine incorporated into the adhesive layer would directly contact the injury mucosa. The outer layer would consisted of non-soluble/non-adhesive polymers that provide durability, protection and directs the delivery of benzocaine toward the lesion."); col. 4:67-5:27; col. 10:19-30 ("The extruded film of claim 1 in multi-layer laminated form, which in addition to the bioadhesive layer also contains an outer protective-barrier membrane layer.").

Valentini '029: Abstract ("In particular, tubular channels which have a smooth inner surface and longitudinally oriented trabeculae result in significantly larger regenerated nerve cables and higher numbers of regenerated myelinated axons."); Figure 3; col. 2:32-35 ("Medical devices employing such selectively permeable materials, particularly semipermeable tubular devices having smooth inner skins, are disclosed for use in regenerating nerves."); col. 2:58-3:14; col. 5:33-41; col. 6:14-24.

Bawa '279: Col. 6:40-44; col. 12:29-34.

Wood '066: Col. 7:51-65 ("The PVA cryogel bandage may be supported by a woven or non-woven fabric of film support."); col. 23:15-23.

Lambert '246: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 2:15-34; col. 2:53-65; col. 3:50-54; col. 10:51-54; col. 11:41-44; col. 12:23-26.

Bellamkonda '029: Fig. 6.

Dayton '382: Abstract; col. 4:4-10; col. 5:50-60; col. 6:64-7:7; col. 8:18-19; col. 8:64-65.

Burt '036: Page 14:9-27; p.21:2-4; p.21:25-22:6 ("Stents may be coated with anti-angiogenic compositions or anti-angiogenic factors of the present invention using a variety of methods . . .").

Goldin '568: Figs. 5A-5F; col. 9:7-12 (" . . . a substance that, when implanted in or juxtaposed against a living body . . ."); col. 22:46-23:3.

Palmaz '665: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3: 55-65 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter..."); col.3:47-51 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway.").

Palmaz '762: Col.3:65-4:2 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 10: 28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '337: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3: 52-56 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5: 19-21; Figures 5 and 6; col. 9: 24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Zaffaroni '254: Col. 7: 18-25 ("Secondly, the carrier contacts and bathes the inner surface of wall 11 for facilitating drug transfer from the carrier to the wall so that drug molecules can dissolve in a diffusive medium in the microporous wall and migrate through it to the outer surface thereof.").

Dev: p.273-74 (disclosing mounting stent on balloon catheter for delivery).

Claim 18 [18A]: The method of claim 17
whereby the stabilizing device is selected from
the group consisting of a stent, an

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intramedullary rod, a catheter, a balloon, and a needle.

Where Found in the Prior References:

Schwartz '823: Abstract ("A radially expandable stent for implantation within a body lumen having a generally cylindrical body with open proximal and distal ends, the cylindrical body comprising a plurality of metal elements joined to allow flexing of the cylindrical body along the longitudinal axis of the body whereby the stent can conform to a curved body lumen and a polymeric film extending between the metal elements of the stent. The stent provides a biocompatible polymeric surface to contact and support a body lumen and also a flexible structure to allow the stent to conform closely to bends in a body lumen."); col. 2:49-53 ("The polymeric film is flexible and preferably an elastic or stretchable film that is capable of conforming to the movement of the metallic stent elements when expanded into contact with a body lumen."); col. 3:58-61 ("The improvement of the present invention includes applying to the above-mentioned type of stent a flexible or elastomeric polymeric film which extends between the metal elements."); col. 4:20-24 ("The term 'film' or 'flexible film' herein therefore means that, as applied to the metal stent elements in a thin cross section, the film is capable of flexing or stretching to preserve the radial expandability and axial flexibility of the implanted stent."); col. 5:59-6:2; col. 6:17-38; col. 6:40-43; col. 6:59-62 ("The flexible film can be applied as a sheath to the metal stent elements after which the stent can be compressed, attached to a catheter, and delivered through a body lumen to a desired location."); col. 8:27-32.

Scott '928: Abstract ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent and a thickness to allow controlled release of the drug. Also provided is a method of preventing thrombosis and promoting and inhibiting vascular growth in a subject comprising inserting a stent encompassed by the sheath of the invention into a vessel of the subject."); Fig. 3; col. 4:58-64 ("This invention provides a sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen into which the stent has been inserted, comprising a polymer and a drug incorporated within the polymer, the polymer sheath encompassing at least a portion of the stent. The sheath also has a thickness to allow controlled release of the drug."); col. 5:26-33; col. 6:37-45 ("The invention also provides a kit comprising the sheath and a stent. Also disclosed is a device comprising a stent encompassed by the sheath. The initial prototype is a sleeve of polymer, either degradable or non-degradable, that covers the entire stent (Fig. 3). Modifications of the polymer coating include a ring that encompasses the proximal portion of the stent, single or multiple strips that cover a portion of the stent, or a polymer coating with perforations."); col. 6:49-59 ("Also disclosed is a method of preventing thrombosis in a subject comprising inserting a stent encompassed by the sheath into a vessel of the subject. In addition, a method of promoting vascular cell growth in a subject is provided comprising inserting a stent encompassed by a sheath containing a promoter of vascular growth into a vessel of a subject. Finally, the invention provides a method of inhibiting vascular cell growth in a subject comprising inserting a stent encompassed by a sheath containing an inhibitor of vascular cell growth into a vessel of the subject."); col. 8:58-60; col. 10:24-33 ("In combination, a hollow tubular stent having a

predetermined length and a separate sheath removably encompassing at least a portion of said hollow tubular stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow controlled release of the drug."); col. 12:9-12; col. 12:13-22 ("25. A kit comprising a hollow tubular stent and a separate sheath for removably encompassing at least a portion of the stent to locally deliver at least one drug to an area selected from the group consisting of an arterial wall and an arterial lumen into which the stent has been inserted, comprising at least one polymer and at least one drug incorporated within the polymer, the sheath removably encompassing at least a portion of the stent and having a thickness to allow Controlled release of the drug.").

Tartaglia '113: Abstract ("The drug loaded stent includes an expandable stent structural member, and a planar sheet of polymeric material attached to the outside of the expandable stent structural member. The polymeric material is preferably bioabsorbable, and loaded or coated with a therapeutic agent or drug to reduce or prevent restenosis in the vessel being treated."); Col. 1:7-10 ("This invention relates generally to expandable intraliminal vascular grafts, generally referred to as stents, and more particularly concerns metal stents wrapped with a polymer film capable of carrying and releasing therapeutic drugs."); col. 1:25-38 ("Since it is often useful to provide localized therapeutic pharmacological treatment of a vessel at the location being treated with the stent, it would be desirable to combine such polymeric materials with existing stent structures to provide a stent with the capability of absorbing therapeutic drugs or other agents, for placement and release of the therapeutic drugs or other agents, for placement and release of the therapeutic agents at a specific intravascular site. The present invention meets this need."); col. 1:42-50 ("Briefly, and in general terms, the present invention provides for a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. Since the polymer film is wrapped on the outside of the stent, and is not needed to provide structural strength to assist in opening the flow path of the vasculature or other body lumen where the stent is to be placed, the drug-containing section can be specially formulated for its specific function of delivering drugs locally."); col. 2:3-55; col. 3:30-32; col. 3:36-39 ("Fig. 9 is a plan view of a sheet of polymeric material in another alternative embodiment including elastic strips for securing the polymeric material wrapped around a stent structural member;"); col. 3:40-41; col. 3:51-54 ("Fig. 14 is a plan view of a sheet of polymeric material in a further alternative embodiment including attachment tabs for securing the polymeric material to a stent structural member;"); Fig. 15; col. 3:55-57 ("Fig. 15 is an elevational view of a drug loaded stent wrapped with the sheet of polymeric material of Fig. 14 and mounted on a balloon dilation catheter for delivery."); Fig. 16; col. 3:58-60 ("Fig. 16 is an enlarged partial sectional view of the drug loaded stent of Fig. 15 showing the sheet of polymeric material wrapped around a slotted tube stent structural member."); col. 4:15-24; col. 4:25-46 ("The planar sheet of polymeric material is preferably adapted to uncoil and expand to match the expansion of the stent structural member. . . The stent can be mounted on a balloon dilatation catheter, for deployment of the stent in the vasculature of the patient."); col. 4:47-5:3; col. 5:4-9; col. 5:15-17; col. 5:18-25; col. 5:25-31; col. 5:36-48 ("A representative stent structural member with which a sheet of polymeric material can be combined according to the principles of the invention is illustrated in Fig. 8."); col. 6:26-65 ("In another currently preferred embodiment illustrated in Figs. 9-13, the stent that can be drug loaded comprises a stent metal structural member, such as the stent structural member

illustrated for example in Fig. 8, and a planar sheet or film of polymeric material, preferably including a plurality of apertures, as will be further explained below."); col. 7:42-53; col. 7:56-62 ("The elastic material attached over the coil of polymeric material helps keep the coil of drug loaded material snug on the stent structural member before it is expanded, and guides its linear expansion during inflation of a balloon dilatation catheter used for deployment of the stent and polymeric drug loaded material in the vasculature or other body lumen of a patient."); col. 8:1-57; col. 9:12-18; col. 9:19-22; col. 10:12-30.

Wolff '208: Col. 2:12-16 ("In all cases, the prostheses of the invention require the presence of an elutable drug compounded to the prosthesis itself. With conventional metal stents, the invention requires a drug-carrying coating overlying at least a portion of the metal."); col. 6:56-58 ("The stent shown in Figs. 2 and 4 is a metallic malleable design which may be forced against a lumen wall by a balloon catheter which fixes it into position."); col. 6:59-62 ("The exterior surface of the metal filaments would include a coating with a drug-eluting polymer described previously."); col. 9:39-42 ("The device is fixed into place either by radial expansion in devices such as shown in Fig. 1 or are deformed by a balloon catheter in the case of devices in accordance with Fig. 2."); col. 9:60-10:3 ("In yet another embodiment of the invention, a purely polymeric prosthesis such as that having the configuration shown in Fig. 1 can be combined with an expandable metal stent to provide additional support for the prosthesis. . . . By including a metal stent within the lumen of the polymeric prosthesis, the polymeric prosthesis is effectively held against the wall of the body lumen by the strength of the metal stent."); col. 10:3-45 ("The stents are arranged on the distal end of the catheter such that the catheter can provide remote, transluminal deployment of the stents, with the metal stent inside the polymeric stent, from an entry point into a selected portion of the body lumen to be treated and also remote actuation of an expansion mechanism from the proximal end of the catheter. The expansion mechanism (e.g. a balloon or the like if the metal stent is made of malleable metal for balloon expansion or a release mechanism if the metal stent is a self-expanding stent made from a resilient metal) is one capable of providing radial expansion of the metal stent body to bring the metal stent into supporting contact with the polymeric stent body and also to press the polymeric stent body so that it expands radially into contact with the wall of the body lumen."); col. 10:46-59; col. 10:59-11:20; col. 11:50-53.

Berg '354: Page 2:3-4 ("This invention relates to intravascular stents for treatment of injuries to blood vessels and particularly to stents having a framework onto which a therapeutic substance or drug is applied."); p. 2:43-53 ("Viewed from a further aspect the invention provides the use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug-eluting surface coating."); p.2:55-3:7; p. 3:31-34; p.3:54-55 ("The solution is applied to the stent and the solvent is allowed to evaporate, thereby leaving on the stent surface a coating of the polymer and the therapeutic substance."); p. 6:6-11; p. 6:17-19; p. 6:53-55 ("The use of a solution containing a dissolved polymer and a dispersed therapeutic substance for the manufacture of a therapeutic agent comprising an expandable intravascular stent having multiple layers of a polymeric drug eluting surface coating.").

Ding '536: Col. 1:24-32 ("The present invention relates generally to providing biostable elastomeric coatings on the surfaces of implants which incorporate biologically active species

having controlled release characteristics in the coating particularly to provide a non-thrombogenic surface during and after timed release of the biologically active species. The invention is particularly described in terms of coating on therapeutic expandable stent prostheses for implantation in body humans, e.g., vascular implantation."); col. 3:19-27 ("Accordingly, it is primary object of the present invention to provide a coating and process for coating a stent to be used as a deployed stent prostheses, the coating being capable of effective controlled long-term delivery of biologically active materials."); col. 3:50-55 ("The present invention provides a relatively thin layered coating of biostable elastomeric material containing an amount of biologically active material dispersed therein in combination with a non-thrombogenic surface that is useful for coating the surfaces of prostheses such as deployable stents."); col. 12:20-23 ("It will be appreciated that the mechanism of incorporation of the biologically active species into a thin surface coating structure applicable to a metal stent is an important aspect of the present invention."); col. 13:13-26 ("A medical device having at least a portion which is implantable into the body of a patient, wherein at least a part of the device portion is metallic and at least part of the metallic device portion is covered with a coating for release of at least one biologically active material . . .").

Dinh '227: Col. 3:41-46 ("Fig. 1 is an elevational view of a balloon catheter with a metallic stent including a fibrin coating according to the present invention. . ."); Fig. 1; Fig. 2; col. 3:64-65; Fig. 10; col. 5:3-7; col. 6:56-67 ("The inclusion of a polymer in intimate contact with a drug on the underlying stent structure allows the drug to be retained on the stent in a resilient matrix during expansion of the stent and also slows the administration of drug following implantation."); col. 7:10-21; col. 7:56-64 ("In another embodiment of the invention, the coating of polymer and drug on the stent is achieved by forming a first fibrin layer on the stent body which incorporates the therapeutic substance and then applying a second layer of fibrin."); col. 8:26-43 ("The stent can also have underlying polymeric or metallic structural elements onto which the fibrin is applied or the stent can be a composite of fibrin intermixed with a polymer."); col. 8:49-60; col. 9:49-50 ("The resulting fibrin stent includes the stent embedded in a very thin elastic film of fibrin."); col. 9:59-63; col. 10:29-31 ("The metal stent portion mentioned above may be eliminated to make a fibrin tube which can be placed on a balloon catheter and expanded into place in a body lumen."); col. 11:60-62 ("It will be readily appreciated that a fibrin stent with an attached metallic framework can be readily provided by this molding method."); col. 12:24-28.

Domb '055: Abstract ("Preferred polymeric coatings are thin, well adhered to the underlying device, and formed of a biocompatible, non-bioerodible polymer such as polyurethane or ethylene vinyl acetate."); col. 1:12-15 ("This invention relates to invasive medical devices for delayed/sustained release of pharmaceutical compositions from a polymer that is coated or incorporated into the devices."); col. 4:33-36; col. 5:24-27 ("Devices are provided having a polymer coating incorporating compounds inhibiting inflammation and infection, along with subsequent tissue growth onto and around the device."); col. 5:35-38; col. 5:46-48; col. 5:60-6:1; col. 6:3-7; col. 7:10-20; col. 7:40-52; col. 9:15-30; col. 9:55-10:2; col. 10:21-52; col. 10:60-11:11; col. 11:27-35 ("A medical device for implantation into tissue comprising, in combination, the device having exterior surfaces, a biocompatible, nonbioerodible polymer dissolved in a solvent to form a solution, the solution being disposed on the exterior surface of the device and the solvent removed to form a uniform coating on the medical device,

the polymer coating having a biologically active agent sorbed therein to be released over a period of at least twenty-four hours by diffusion when implanted in the tissue, wherein said biologically active agent is iodine."); col. 12:11-22; col. 12:32-42.

Fox '096: Col. 1:33-36 ("In addition, antimicrobial compositions useful as coatings for medical devices or for forming the device itself are disclosed . . ."); col. 2:9-21 ("In accordance with the first embodiment of the present invention, there is provided a method of preparing an infection-resistant medical device which comprises (a) preparing a coating vehicle by dissolving a matrix-forming polymer selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof in at least one solvent therefor; (b) incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition; (c) coating a medical device with the coating composition; and (d) drying the coated medical device."); col. 2:48-65; Col. 15:20-33 ("It will be further understood that the invention does not require coating both the inside and outside of medical devices, especially catheters. . . . There may be instances when, for example, a coating containing an antimicrobial agent and heparin is applied only on the outside of an I.V. catheter used for providing blood to a patient. In other instances, it is advantageous to apply a coating with the anti-coagulant on the inside of the catheter to prevent clotting blockages."); col. 16:16-23 ("The catheter was dipped in the coating vehicle while the vehicle was being continuously agitated to insure a uniform suspension. The coated catheter was then dried. A tightly adherent coating on the catheter was thus provided."); col. 19:11-16; col. 22:31-37; col. 30:49-53; col. 36:65-37:7.

Hunter '981: Col. 1:12-17 ("The present invention relates generally to compositions and methods for treating cancer and other angiogenic-dependent diseases, and more specifically, to compositions comprising anti-angiogenic factors and polymeric carriers, stents which have been coated with such compositions, as well as method for utilizing these stents and compositions."); col. 4:20-23; col. 4:38-41; col. 5:14-16; col. 5:17-22; col. 5:28-32; col. 22:3-6 ("As noted above, the present invention also provides stents, comprising a generally tubular structure . . . the surface of which is coated with a composition as described above."); col. 22:23-39 ("Representative examples of stents include those described in . . ."); col. 22:40-64 ("Stents may be coated with anti-angiogenic compositions or anti-angiogenic factors of the present invention in a variety of manners, including for example: (a) by directly affixing to the stent an anti-angiogenic composition (e.g., by either spraying the stent with a polymer/drug film, or by dipping the stent into a polymer/drug solution) . . . (d) by inserting the stent into a sleeve of mesh which is comprised of or coated with an anti-angiogenic composition . . ."); col. 23:6-12; col. 23:46-51; col. 24:45-51; col. 24:66-25:5; col. 25:24-29; col. 25:48-54; col. 26:24-29; col. 69:22-26 ("In this study, strecker stents were coated with an EVA polymer containing paclitaxel at concentration of 33%, 10%, and 2.5% and were tested for their ability to inhibit angiogenesis on the CAM."); 86:56-59; col. 87:11-22; col. 88:19-26.

Kowligi '782: Abstract ("A non-porous coated PTFE graft includes a PTFE tube having a conventional porous inner cylindrical wall and a non-porous elastomeric coating applied over at least a portion of the outer cylindrical wall of the PTFE tube to render such portion of the outer cylindrical wall non-porous."); col. 2:38-47; col. 2:53-67; col. 3:7-12; col. 3:27-37; Col. 2:60-67 ("PTFE tube 32 includes an inner cylindrical wall and an opposing outer cylindrical wall. As

shown in Fig. 2, outer cylindrical wall 36 is coated entirely around its circumference by a uniformly thick coating of a biocompatible elastomer."); col. 5:4-7; col. 5:16-21.

Lambert '922: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 3:49-53; col. 5:57-61; col. 7:55-58; col. 11:52-56 ("The method in accordance with claim 1, wherein the substrate is selected from the group consisting of a metallic stent, a heart valve, a metallic prosthesis, a prosthetic joint, a pacemaker, a catheter, a balloon coating, an ocular implant and a contact lens").

Lambert '308: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); p. 10:17-21; p. 13:20-24; claim 8 ("The method according to claim 1, wherein the substrate is selected from a metallic stent, a heart valve, a metallic prosthesis, a prosthetic joint, a pacemaker, a catheter, a balloon coating, an ocular implant or a contact lens").

WO 94/21309: Abstract ("A new method to treat blood vessel stenosis using endovascular prostheses which are coated with amphiphilic polyurethanes to which medicines can be coupled."); page 1:4-8; p. 2:29-30; p. 3:11-13.

Myler '563: Col. 2:13-15; col. 4:30-43 ("In a preferred embodiment, the interior and exterior walls of stent 10 are enclosed in a thin polymeric envelop."); col. 4:44-52 ("The envelope may be produced, for example, by inserting the stent into a preformed tubular envelope having one open end and sealing the envelope closed, or other techniques within the skill in the art."); col. 5:1-16; col. 5:50-54; col. 12:63-13:1; col. 13:5-14.

Palmaz '417: Col. 11:3-8 ("With reference now to Figs. 5 and 6, prostheses, or grafts of the type previously described in connection with Figs. 1A and 1B are shown, and the tubular members of grafts, or prostheses, have a biologically inert or biologically compatible coating placed upon wall surfaces of tubular shaped members."); col. 13:51-53 ("The method of claim 1, wherein at least one prosthesis is provided with a biologically compatible coating on the outer surface of the prosthesis.").

Wood '066: Col. 7:51-65 ("The PVA cryogel bandage may be supported by a woven or non-woven fabric of film support."); col. 23:15-23.

Strecker '746: Abstract; col. 1:63-2:2; col. 2:12-15 ("The present invention on the other hand exploits a wrapping material that plastically deforms as it expands and accordingly exerts no restoration force on the stent, ensuring persistent expansion."); col. 2:21-32 ("This embodiment has a wrinkled lining around the as yet unexpanded stent."); col. 2:33-38; col. 2:47-53; col. 2:59-64; col. 2:65-3:4 ("[T]he lining can be a flexible tubular membrane or sleeve

wrapped around the prosthesis and secured."); col. 6:30-64; col. 7:16-35; col. 8:4-9; col. 8:19-10:19; Figs. 7 & 8.

Lambert '246: Abstract ("In accordance with the present invention, there are provided prosthetic articles having polyurethane coatings with biologically active compounds incorporated within the interstices of the polymer. . . . Thus a polyurethane coating is applied to a prosthetic article [and] [u]pon long-term exposure of the prosthetic article of the invention to physiological conditions, the biologically active compound is slowly released by the treated polymer."); col. 2:15-34; col. 2:53-65; col. 3:50-54; col. 10:51-54; col. 11:41-44; col. 12:23-26.

Dayton '382: Col. 4:4-10; col. 5:50-60; col. 8:64-65.

Burt '036: p.21:25-22:6 ("Stents may be coated with anti-angiogenic compositions or anti-angiogenic factors of the present invention using a variety of methods . . .").

Palmaz '665: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3: 55-65 ("The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter..."); col.3:47-51 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway.").

Palmaz '762: Col.3:65-4:2 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 10: 28-43 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Palmaz '337: Abstract ("The graft may be a wire mesh tube, having a biologically inert coating thereon."); col.3: 52-56 ("A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway."); col. 5: 19-21; Figures 5 and 6; col. 9: 24-32 ("...and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials.").

Dev: p.273-74 (disclosing mounting stent on balloon catheter for delivery).